

PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Idacio[®] (pronounced)
<< i-DAS-i-oh >>
Adalimumab Injection
Adalimumab, 40 mg / 0.8 mL (50 mg / mL) Sterile Solution for Subcutaneous Injection
Single Use Prefilled Pen

Idacio is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humira[®]. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Read this carefully before you / your child start taking Idacio and each time you / your child get a refill. This leaflet is a summary and will not tell you / your child everything about this drug. Talk to your / your child's healthcare professional about your / your child's medical condition and treatment and ask if there is any new information about Idacio.

Serious Warnings and Precautions

Before starting, during and after treatment with Idacio, you / your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test. Any medicine can have side effects. Like all medicines that affect your / your child's immune system, Idacio can cause serious side effects. The possible serious side effects include:

- **Allergic reactions:** If you / your child develop a severe rash, swollen face or difficulty breathing while taking Idacio, call your / your child's doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab injection. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab injection is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab injection or other TNF-blockers. Some patients receiving adalimumab injection have developed types of cancer called non-melanoma skin cancer. Tell your / your child's doctor if you / your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you / your child take Idacio or other TNF-blockers, your / your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab injection, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you / your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your / your child's cheeks or arms that gets worse in the sun, call your / your child's doctor right away. Your / your child's doctor may decide to stop your / your child's treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab injection or other TNF-blockers. Signs that you / your child could be experiencing a problem affecting your / your child's nervous system include: numbness or tingling, problems with your / your child's vision, weakness in your / your child's legs, and dizziness.
- **Serious infections:** There have been rare cases where patients taking adalimumab injection or other TNF-blocking

agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.

- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you / your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your / your child's doctor right away.

What is Idacio used for?

Idacio treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis, and familiar with the Idacio efficacy and safety profile.

Idacio is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- children 13 to 17 years weighing ≥ 40 kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed Idacio to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Idacio. If you have ulcerative colitis or you / your child have Crohn's disease, you / your child will first be given other medicines. If you / your child do not respond well enough to these medicines, you / your child will be given Idacio to reduce the signs and symptoms of your / your child's disease.

How does Idacio work?

Idacio is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. Idacio binds to a specific protein called TNF- alpha (also known as tumor necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your /your child's bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, Idacio decreases the inflammation process of these diseases.

Idacio helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your / your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your / your child's bones and joints. In addition, Idacio helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning

stiffness), and adult and pediatric Crohn's disease or ulcerative colitis (abdominal pain and diarrhea). Idacio may also help normalize childhood growth and pubertal development and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). Idacio may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease.

Idacio is also used to treat inflammatory lesions (nodules and abscesses) in adults and adolescents (12 to 17 years of age, weighing ≥ 30 kg) with hidradenitis suppurativa.

Idacio also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

Idacio helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

Idacio, however, can also lower your / your child's body's ability to fight infections. Taking Idacio can make you / your child more prone to getting infections or make any infection you / your child have worse.

What are the ingredients in Idacio?

Medicinal ingredients: adalimumab injection

Non-medicinal ingredients: citric acid monohydrate, disodium phosphate dihydrate, mannitol, polysorbate-80, sodium chloride, sodium dihydrogen phosphate dihydrate, sodium hydroxide, trisodium citrate dihydrate and water for injection..

Idacio comes in the following dosage forms:

- Single-use, 1 mL auto-injector containing 40 mg adalimumab injection in 0.8 mL sterile solution (50 mg/mL). All contents of the carton do not contain natural rubber latex.

Do not use Idacio if:

You / your child should not take Idacio if you / your child have:

- an allergy to any of the ingredients in Idacio (see **What are the ingredients in Idacio?** section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

To help avoid side effects and ensure proper use, talk to your / your child's doctor or pharmacist before you / your child take Idacio. Talk about any health conditions or problems you / your child may have, including if:

- you / your child have or have had any kind of infection including an infection that is in only one place in your / your child's body (such as an open cut or sore), or an infection that is in your / your child's whole body (such as the flu). Having an infection could put you / your child at risk for serious side effects from Idacio. If you are unsure, ask your / your child's doctor.
- you / your child have a history of infections that keep coming back or other conditions that might increase your / your child's risk of infections, including fungal infections.
- you / your child have ever had tuberculosis, or if you / your child have been in close contact with someone who has had tuberculosis. If you / your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your / your child's doctor right away. Your / your child's doctor will need to examine you / your child for tuberculosis and perform a skin test.
- you / your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your / your child's body. If you / your child take Idacio these may become active or more severe. If you don't know if you / your child have lived in or travelled to an area where these infections are common, ask your / your child's doctor.
- you / your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of

appetite, joint pain, fever, dark brown-colored urine, vomiting, and abdominal pain. If you / your child experience any of these signs and symptoms, contact your / your child's doctor immediately. These symptoms may occur several months after starting therapy with Idacio.

- you / your child experience any numbness or tingling or have ever had a disease that affects your / your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you / your child have or have had heart failure.
- you / your child are scheduled to have major surgery or dental procedures.
- you / your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting Idacio.
- you / your child are taking other medicines for your / your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You / your child can take other medicines provided your / your child's doctor has prescribed them or has told you / your child it is acceptable that you / your child take them while you / your child are taking Idacio. It is important that you tell your / your child's doctor about any other medicines you / your child are taking for other conditions (for example, high blood pressure medicine) before you / your child start taking Idacio.
- you / your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you / your child are pregnant or could become pregnant
 - you / your child are breast-feeding or plan to breast-feed.

If you / your child are not sure or have any questions about any of this information, ask your / your child's doctor.

Other warnings you / your child should know about:

If you / your child received Idacio while pregnant, your/her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of Idacio received during pregnancy. It is important that you/she tell your / her baby's doctors and other healthcare professionals about your / her Idacio use during pregnancy so they can decide when your / her baby should receive any vaccine.

Tell your / your child's healthcare professional about all the medicines you / your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Idacio:

You / your child should not take Idacio with:

- other TNF-blockers such as Enbrel[®], Remicade[®], Cimzia[®], or Simponi[®]
- abatacept (Orencia[®])
- anakinra (Kineret[®])

If you / your child have questions, ask your / your child's doctor.

How to take Idacio:

Idacio is administered by injection under the skin (by subcutaneous injection).

Usual dose:

Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:

- weighing 10 kg to less than 30 kg: the recommended dose of Idacio is 20 mg every other week.
- weighing 30 kg or more: the recommended dose of Idacio is 40 mg every other week.

Patients who require a dose of less than 40 mg must use the vial presentation of Idacio, as the Pen cannot deliver doses less than 40 mg.

Adults with Crohn's Disease or Ulcerative Colitis:

- The recommended dose is 160 mg at Week 0, followed by 80 mg at Week 2 administered by subcutaneous injection. The first dose of 160 mg can be given in one day (four 40mg injections) or split over two consecutive days (two 40 mg injections each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections in one day. The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

Children, 13 to 17 years of age weighing \geq 40 kg, with Crohn's disease:

- The recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, you / your child will begin a maintenance dose of 20 mg every other week. Depending on your / your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

Patients who require a dose of less than 40 mg must use the vial presentation of Idacio, as the Pen cannot deliver doses less than 40 mg.

Adults with Hidradenitis Suppurativa:

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later administered by subcutaneous injection. The first dose of 160 mg at Week 0 can be given in one day (four 40 mg injections) or split over two consecutive days (two 40 mg injections). The second dose of 80 mg at Week 2 is given as two 40 mg injections in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

Adults with Psoriasis or Uveitis:

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

Adolescents, 12 to 17 years of age weighing \geq 30 kg, with Hidradenitis Suppurativa:

- The recommended initial dose is 80 mg administered by subcutaneous injection, followed by 40 mg every other week starting one week later. Depending on your / your child's response, the doctor may increase the dose to 40 mg every week.

Children, from 2 years of age with Uveitis:

- weighing less than 30 kg: the usual dose of Idacio is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of Idacio is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

Patients who require a dose of less than 40 mg must use the vial presentation of Idacio, as the Pen cannot deliver doses less than 40 mg.

Overdose:

If you / your child accidentally inject Idacio more frequently than instructed, contact your / your child's doctor or local poison control centre right away.

Missed Dose:

If you / your child forget to give yourself/your child an injection, you / your child should inject the missed dose of Idacio as soon as you / your child remember. Then administer the next dose as you / your child would have on the originally scheduled date.

What are possible side effects from using Idacio?

These are not all the possible side effects you / your child may feel when taking Idacio. If you / your child experience any side effects not listed here, contact your / your child's healthcare professional. Please also see Warnings and Precautions.

Like all medicines, Idacio can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment. Tell your / your child's doctor immediately if you / your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain (this is possibly indicative of new or worsening heart failure)
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets.

Tell the doctor as soon as possible if you / your child notice any of the following:

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus (this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection)
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your / your child's urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss
- pain in the abdomen or chest

Serious side effects and what to do about them			
Symptom/effect	Talk with the doctor or pharmacist		Stop taking drug and call the doctor or pharmacist
	Only if severe	In all cases	
VERY COMMON Injection site reaction		√	
COMMON Cough and cold symptoms, including sore throat		√	
Headache	√		
Rash		√	
Nausea		√	
Pneumonia		√	√
Fever		√	
Abdominal pain	√		
UNCOMMON Tuberculosis		√	√
Other serious infections		√	√
Nerve disorder		√	√
Appendicitis		√	√
Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		√	√
Bladder infection (painful urination)		√	√
Hepatitis [jaundice (yellow skin, dark urine), abdominal pain, tiredness]		√	√

If you / your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your / your child's daily activities, talk to your / your child's healthcare professional.

General Advice About Prescription Medicines

Talk to your / your child's doctor or other healthcare provider if you / your child have any questions about this medicine or your / your child's condition. Medicines are sometimes prescribed for purposes other than those listed in a **PATIENT MEDICATION INFORMATION** leaflet. If you / your child have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you / your child information about this medicine that was written for health care professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at 1-877-821-7724

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffectcanada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2 and 8°C (in a refrigerator) in the original carton until ready to use. **DO NOT FREEZE.** Keep the prefilled pen in the outer carton to protect from light. Refrigerated Idacio prefilled pen remain stable until the expiration date printed on the auto-injector. Do not use beyond the expiration date.

When needed, for example when you / your child are travelling, an Idacio prefilled pen can be stored at room temperature (up to 25°C/77°F) for a single maximum period of 14 days – be sure to protect it from light.

Once taken out of the refrigerator for room temperature storage, an Idacio prefilled pen must be used within 14 days, even if it is put back in the refrigerator. If not used within 14 days, the Idacio prefilled pen must be discarded. You should record the date when the Idacio prefilled pen is first removed from the refrigerator. Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.

Keep out of reach and sight of children.

If you want more information about Idacio:

- Talk to your / your child's healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website (<https://www.fresenius-kabi.com/en-ca>), or by calling 1-877-821-7724

This leaflet was prepared by Fresenius Kabi Canada Ltd. 165 Galaxy Blvd, Suite 100, Toronto, ON M9W 0C8

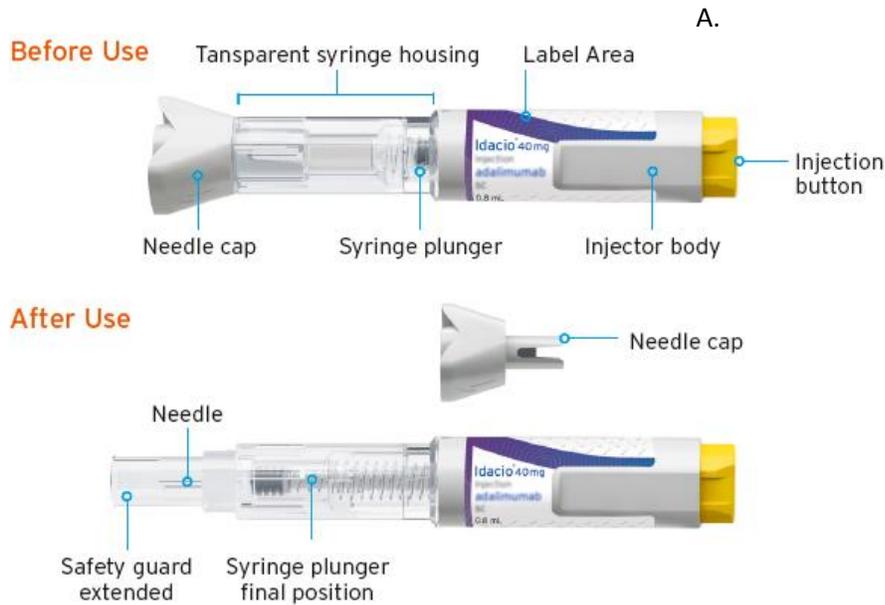
Date revised: October 30, 2020

Idacio is a trademark of Fresenius Kabi AG; Fresenius Kabi AG is a trademark of Fresenius SE.

Instructions for Use:

For your / your child's protection, it is important that you follow these instructions.

Get Familiar with your Idacio Prefilled Pen



Step 1: Prepare for your Injection

Each box of Idacio prefilled pens comes with two pens.

- Prepare a clean flat surface, such as a table or countertop, in a well-lit area.
- You will also need an alcohol pad (**not included** in the box), a cotton ball or gauze, and a sharps disposal container.
- Remove the box from the refrigerator.



- Check the expiration date on the side of the box. Do not use if expiration date has passed.
- Take a prefilled pen out of the original box:
 - place two fingers on the label area
 - pull the prefilled pen straight up and out of the packaging (Fig. A).Put it on a clean flat surface.

- f) Place the remaining prefilled pen in its original box back in the refrigerator.

Refer to Storage Information for how to store your unused prefilled pen.

- g) Leave the prefilled pen at room temperature for 30 minutes to allow the medicine to warm up. Injecting cold medicine can be painful (Fig. B).



Fig. B

Do not warm the prefilled pen any other way, such as in a microwave, hot water, or direct sunlight. **Do not** remove the needle cap while allowing syringe to reach room temperature.

Step 2: Wash your hands

Wash your hands well with soap and water and dry them. Gloves will not replace the need for washing hands.

Step 3: Check the Prefilled Pen

- a) Check the transparent syringe housing to make sure that:

- The liquid is clear, colorless, and free of particles
- The glass syringe is not cracked or broken

Do not use the prefilled pen if the liquid contains particles, or is cloudy or if it is colored, or has flakes in it or shows any sign of damage. If so, throw it away in a sharps disposal container and contact your healthcare Professional or pharmacist.

- b) Check the label to make sure that:

- The name on the prefilled pen says Idacio (Fig. C).
- The expiration date on the prefilled pen has not passed (Fig. I).

Do not use the prefilled pen if the name on the label is not Idacio and/or the expiration date on the label has passed. If so, throw away the prefilled pen in a sharps disposal container and contact your healthcare professional or pharmacist.

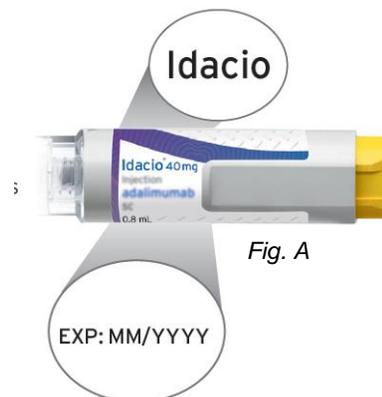


Fig. A

Step 4: Choose and clean the injection site

- a) Choose an injection site (Fig. D) on:
- Top of the thighs.
 - Abdomen (inject at least 5 centimeters away from the belly button).
- b) Choose a different site (at least 2.5 centimeters away from the previous injection site) each time to reduce redness, irritation or other skin problems.

Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks. If you have psoriasis, **do not** inject into any lesions or red, thick, raised or scaly patches.



Fig. D

- c) Wipe the skin of your injection site with an alcohol pad to clean it. **Do not** blow on or touch the injection site after cleaning.

Step 5: Give your Injection

- a) Remove the needle cap
- Hold the prefilled pen upwards and pull the needle cap straight off (Fig. E). You may see drops of liquid at the needle tip.
 - Throw away the needle cap.
- Do not** twist the cap. **Do not** recap the prefilled pen.

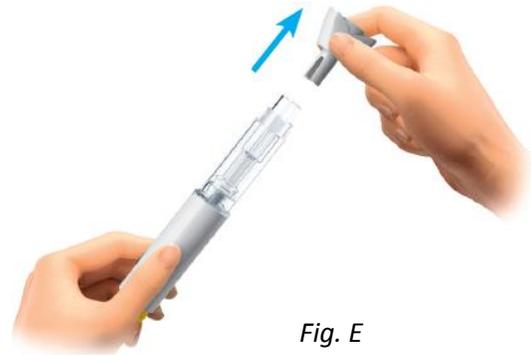


Fig. E

- b) Position the prefilled pen
- Hold the pre-filled pen so that you can see the transparent syringe housing.
 - Place your thumb above (not touching) the yellow injection button (Fig. F).



Fig. F

- Place the prefilled pen against your skin at a 90° angle (Fig. G).



Fig. G

- Push and hold the prefilled pen firmly against your skin until the safety guard is fully depressed. This will unlock the injection button.

c) Administer the Injection

- Push the injection button (Fig. H). You will hear a loud click, which means the injection has started.
- Continue to HOLD the prefilled pen firmly.
- WATCH the syringe plunger to make sure it moves all the way down to the bottom (Fig. H).

Do not lift the prefilled pen from the skin until the plunger has moved all the way down and all the liquid has been injected.

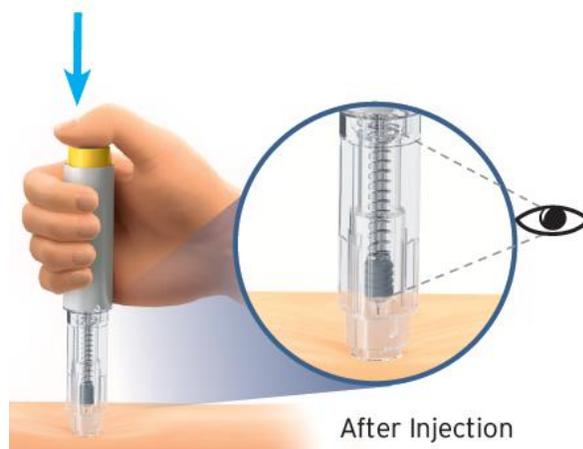


Fig. H

- When the syringe plunger has moved to the bottom and has stopped moving, continue holding it for 5 seconds.
- Lift the prefilled pen from your skin (Fig. I). The safety guard will slide down and lock into place to protect you from the needle (Fig. I).



Fig. I

Call your healthcare professional or pharmacist if you have any problem.

- d) If there is blood or liquid on the injection site, gently press a cotton ball or gauze on the skin

Step 6: Throw away your prefilled Pen

Throw away your used prefilled Pen in a sharps disposal container right away after use

Step 7: Record your Injection

To help you remember when and where to do your next injection, you should keep a record of the dates and injection sites used for your injections (Fig. J).

Fig. J



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- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab injection. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab injection is not clear.
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- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab injection or other TNF-blockers. Signs that you / your child could be experiencing a problem affecting your / your child's nervous system include: numbness or tingling, problems with your / your child's vision, weakness in your / your child's legs, and dizziness.
- **Serious infections:** There have been rare cases where patients taking adalimumab injection or other TNF-blocking

agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.

- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you / your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your / your child's doctor right away

What is Idacio used for?

Idacio treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (JIA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), adult and pediatric Crohn's disease (CD), ulcerative colitis (UC), adult and adolescent hidradenitis suppurativa (HS), psoriasis (Ps) or adult and pediatric uveitis, and familiar with the Idacio efficacy and safety profile.

Idacio is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis.
- children 13 to 17 years weighing ≥ 40 kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed Idacio to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Idacio. If you have ulcerative colitis or you / your child have Crohn's disease, you / your child will first be given other medicines. If you / your child do not respond well enough to these medicines, you / your child will be given Idacio to reduce the signs and symptoms of your / your child's disease.

How does Idacio work?

Idacio is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. Idacio binds to a specific protein called TNF- alpha (also known as tumor necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your / your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your /your child's bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, Idacio decreases the inflammation process of these diseases.

Idacio helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your / your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your / your child's bones and joints. In addition, Idacio helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult and pediatric Crohn's disease or ulcerative colitis (abdominal pain and diarrhea). Idacio may also

help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). Idacio may help improve the work productivity and activity impairment in caregivers of children with Crohn's disease.

Idacio is also used to treat inflammatory lesions (nodules and abscesses) in adults and adolescents (12 to 17 years of age, weighing ≥ 30 kg) with hidradenitis suppurativa.

Idacio also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

Idacio helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

Idacio, however, can also lower your / your child's body's ability to fight infections. Taking Idacio can make you / your child more prone to getting infections or make any infection you / your child have worse.

What are the ingredients in Idacio?

Medicinal ingredients: adalimumab injection

Non-medicinal ingredients: citric acid monohydrate, disodium phosphate dihydrate, mannitol, polysorbate-80, sodium chloride, sodium dihydrogen phosphate dihydrate, sodium hydroxide, trisodium citrate dihydrate and water for injection.

Idacio comes in the following dosage forms:

- Single-use, 1 mL prefilled glass syringe containing 40 mg adalimumab injection in 0.8 mL sterile solution (50 mg/mL). All contents of the carton do not contain natural rubber latex.

Do not use Idacio if:

You / your child should not take Idacio if you / your child have:

- an allergy to any of the ingredients in Idacio (see **What are the ingredients in Idacio?** section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

To help avoid side effects and ensure proper use, talk to your / your child's doctor or pharmacist before you / your child take Idacio. Talk about any health conditions or problems you / your child may have, including if:

- you / your child have or have had any kind of infection including an infection that is in only one place in your / your child's body (such as an open cut or sore), or an infection that is in your / your child's whole body (such as the flu). Having an infection could put you / your child at risk for serious side effects from Idacio. If you are unsure, ask your / your child's doctor.
- you / your child have a history of infections that keep coming back or other conditions that might increase your / your child's risk of infections, including fungal infections.
- you / your child have ever had tuberculosis, or if you / your child have been in close contact with someone who has had tuberculosis. If you / your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your / your child's doctor right away. Your / your child's doctor will need to examine you / your child for tuberculosis and perform a skin test.
- you / your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your / your child's body. If you / your child take Idacio these may become active or more severe. If you don't know if you / your child have lived in or travelled to an area where these infections are common, ask your / your child's doctor.
- you / your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-colored urine, vomiting, and abdominal pain. If you / your child experience any of these signs and symptoms, contact your / your child's doctor immediately. These symptoms may occur several months after starting therapy with Idacio.

- you / your child experience any numbness or tingling or have ever had a disease that affects your / your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you / your child have or have had heart failure.
- you / your child are scheduled to have major surgery or dental procedures.
- you / your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting Idacio.
- you / your child are taking other medicines for your / your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You / your child can take other medicines provided your / your child's doctor has prescribed them or has told you / your child it is acceptable that you / your child take them while you / your child are taking Idacio. It is important that you tell your / your child's doctor about any other medicines you / your child are taking for other conditions (for example, high blood pressure medicine) before you / your child start taking Idacio.
- you / your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you / your child are pregnant or could become pregnant
 - you / your child are breast-feeding or plan to breast-feed.

If you / your child are not sure or have any questions about any of this information, ask your / your child's doctor.

Other warnings you / your child should know about:

If you / your child received Idacio while pregnant, your / her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of Idacio received during pregnancy. It is important that you/she tell your / her baby's doctors and other healthcare professionals about your / her Idacio use during pregnancy so they can decide when your / her baby should receive any vaccine.

Tell your / your child's healthcare professional about all the medicines you / your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Idacio:

You / your child should not take Idacio with:

- other TNF-blockers such as Enbrel[®], Remicade[®], Cimzia[®], or Simponi[®]
- abatacept (Orencia[®])
- anakinra (Kineret[®])

If you / your child have questions, ask your / your child's doctor.

How to take Idacio:

Idacio is administered by injection under the skin (by subcutaneous injection).

Usual dose:

Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:

- weighing 10 kg to less than 30 kg: the recommended dose of Idacio is 20 mg every other week.

- weighing 30 kg or more: the recommended dose of Idacio is 40 mg every other week. Patients who require a dose of less than 40 mg must use the vial presentation of Idacio, as the PFS cannot deliver doses less than 40 mg.

Adults with Crohn's Disease or Ulcerative Colitis:

- The recommended dose is 160 mg at Week 0, followed by 80 mg at Week 2 administered by subcutaneous injection. The first dose of 160 mg can be given in one day (four 40mg injections) or split over two consecutive days (two 40 mg injections each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections in one day. The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

Children, 13 to 17 years of age weighing \geq 40 kg, with Crohn's disease:

- For children weighing \geq 40 kg, the recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, you / your child will begin a maintenance dose of 20 mg every other week. Depending on your / your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection).

Adults with Hidradenitis Suppurativa:

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later administered by subcutaneous injection. The first dose of 160 mg at Week 0 can be given in one day (four 40 mg injections) or split over two consecutive days (two 40 mg injections). The second dose of 80 mg at Week 2 is given as two 40 mg injections in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

Adults with Psoriasis or Uveitis:

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose administered by subcutaneous injection. The first dose of 80 mg can be given as two 40 mg injections.

Children, from 2 years of age with Uveitis:

- weighing less than 30 kg: the usual dose of Idacio is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of Idacio is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

Patients who require a dose of less than 40 mg must use the vial presentation of Idacio, as the PFS cannot deliver doses less than 40 mg.

Overdose:

If you / your child accidentally inject Idacio more frequently than instructed, contact your / your child's doctor or local poison control centre right away.

Missed Dose:

If you / your child forget to give yourself/your child an injection, you / your child should inject the missed dose of Idacio as soon as you / your child remember. Then administer the next dose as you / your child would have on the originally scheduled date.

What are possible side effects from using Idacio?

These are not all the possible side effects you / your child may feel when taking Idacio. If you / your child experience any side effects not listed here, contact your / your child's healthcare professional. Please also see Warnings and Precautions.

Like all medicines, Idacio can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment. Tell your / your child's doctor immediately if you / your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet
- trouble breathing, swallowing
- sudden weight gain (this is possibly indicative of new or worsening heart failure)
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets.

Tell the doctor as soon as possible if you / your child notice any of the following:

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus (this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection)
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your / your child's urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss
- pain in the abdomen or chest

Serious side effects and what to do about them			
Symptom/effect	Talk with the doctor or pharmacist		Stop taking drug and call the doctor or pharmacist
	Only if severe	In all cases	
VERY COMMON Injection site reaction		√	
COMMON Cough and cold symptoms, including sore throat		√	
Headache	√		
Rash		√	
Nausea		√	
Pneumonia		√	√
Fever		√	
Abdominal pain	√		
UNCOMMON Tuberculosis		√	√
Other serious infections		√	√
Nerve disorder		√	√
Appendicitis		√	√
Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		√	√
Bladder infection (painful urination)		√	√
Hepatitis [jaundice (yellow skin, dark urine), abdominal pain, tiredness]		√	√

If you / your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your / your child's daily activities, talk to your / your child's healthcare professional.

General Advice About Prescription Medicines

Talk to your / your child's doctor or other healthcare provider if you / your child have any questions about this medicine or your / your child's condition. Medicines are sometimes prescribed for purposes other than those listed in a **PATIENT MEDICATION INFORMATION** leaflet. If you / your child have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you / your child information about this medicine that was written for health care professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at 1-877-821-7724.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffectcanada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2 and 8°C (in a refrigerator) in the original carton until ready to use. **DO NOT FREEZE.** Keep the prefilled syringe in the outer carton to protect from light. Refrigerated Idacio prefilled syringe remain stable until the expiration date printed on the prefilled syringe. Do not use beyond the expiration date.

When needed, for example when you / your child are travelling, an Idacio prefilled syringe can be stored at room temperature (up to 25°C/77°F) for a single maximum period of 14 days – be sure to protect it from light.

Once taken out of the refrigerator for room temperature storage, an Idacio prefilled syringe must be used within 14 days, even if it is put back in the refrigerator. If not used within 14 days, the Idacio prefilled syringe must be discarded. You should record the date when the Idacio prefilled syringe is first removed from the refrigerator. Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.

Keep out of reach and sight of children.

If you want more information about Idacio:

- Talk to your / your child's healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website (<https://www.fresenius-kabi.com/en-ca>), or by calling 1-877-821-7724.

This leaflet was prepared by Fresenius Kabi Canada Ltd. 165 Galaxy Blvd, Suite 100, Toronto, ON M9W 0C8

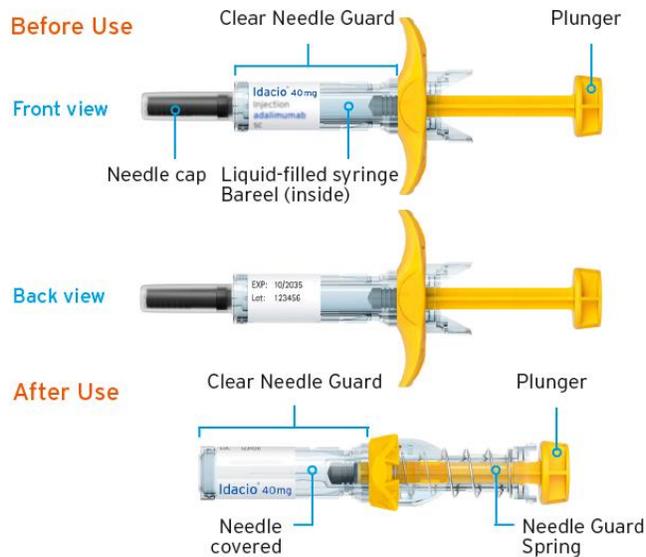
Date revised: July 30, 2020

Idacio is a trademark of Fresenius Kabi AG; Fresenius Kabi AG is a trademark of Fresenius SE.

Instructions for Use:

For your / your child's protection, it is important that you follow these instructions.

Get Familiar with your Idacio Prefilled Syringe



Step 1: Prepare for your Injection

Each box of Idacio prefilled syringe comes with two syringes

- Prepare a clean flat surface, such as a table or countertop, in a well-lit area.
- You will also need an alcohol pad (**not included** in the box), a cotton ball or gauze, and a sharps disposal container.

Open your sharps disposal container so it is ready to use.

- Remove the box from the refrigerator.
- Check the expiration date on the side of the box. **Do not** use if expiration date has passed.

- Do not** pick up the syringe by the plunger or the needle cap. Doing so could damage the syringe or activate the clear needle guard. Take a syringe out of the original box:

- place two fingers on middle of the clear needle guard
- pull the syringe straight up and out of the packaging (Fig. A).



Put it on a clean flat surface.

Fig A

- f) Place the remaining syringe in its original box back in the refrigerator. Refer to Storage information for how to store your unused syringe.
- g) Leave the syringe at room temperature for 30 minutes to allow the medicine to warm up. Injecting cold medicine can be painful (Fig. B). **Do not** warm the syringe any other way, such as in a microwave, hot water, or direct sunlight. **Do not** remove the needle cap while allowing syringe to reach room temperature.



Fig B

Step 2: Wash your hands

Wash your hands well with soap and water and dry them. Gloves will not replace the need for washing hands

Step 3: Check the Syringe

- a) Check the syringe to make sure that:
- The syringe, the clear needle guard, and the needle cap are not cracked or damaged (Fig. C).
 - The needle cap is securely attached (Fig. D).
 - The needle guard spring is not extended (Fig. E).

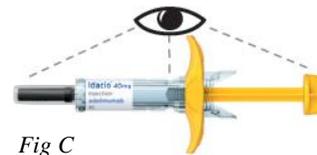


Fig C



Fig D



Fig E

Do not use the syringe if it shows any sign of damage. If so, throw away the syringe in a sharps disposal container and contact your healthcare professional or pharmacist.

- b) Check the liquid to make sure that the liquid is clear, colorless, and free of particles. **Do not** use the syringe if liquid contains particles, or is cloudy or if it is colored or has flakes in it.
- c) Check the label to make sure that:
- The name on the syringe says Idacio (Fig. f).
 - The expiration date on syringe has not passed (Fig. F).

Do not use the syringe if:

- The name on the syringe is not Idacio.
- The expiration date on the syringe has passed.

If so, throw away the syringe in a sharps disposal container and contact your healthcare professional or pharmacist.

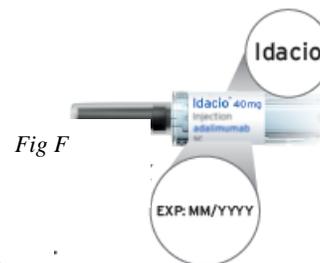


Fig F

Step 4: Choose, clean the injection site

a) Choose an injection site (Fig. G) on:

- Top of the thighs.
- Abdomen (inject at least 5 centimeters away from the belly button).

b) Choose a different site (at least 2.5 centimeters away from the previous injection site) each time to reduce redness, irritation or other skin problems. **Do not** inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks. If you have psoriasis, do not inject into any lesions or red, thick, raised or scaly patches.



Fig G

c) Wipe the skin of your injection site with an alcohol pad to clean it. **Do not** blow on or touch the injection site after cleaning.

Step 5: Give your Injection

- a) Remove the needle cap
- Always hold the syringe by the clear needle guard.
 - Hold the syringe upward and pull the needle cap straight off (Fig. H).

You may see drops of liquid at the needle tip.

Throw away the needle cap. **Do not** touch the needle.



Fig H

- b) Pinch the skin
- Hold the syringe like a pencil.
 - With your other hand gently pinch skin (without squeezing) to avoid injecting into a muscle (Fig. I).



Fig I

- c) Insert the needle
- With a quick, short motion, push the needle all the way into the skin at an angle between 45° and 90° (Fig. J).
 - After the needle is inserted, release the pinched skin.



Fig J

d) Inject: Use your thumb to gently push plunger all the way down (Fig. K).



Fig K

- Give plunger a final push to ensure the full dose has been injected (Fig. L).
 - Hold the syringe firmly without moving it, at the same angle (Fig. L).
- Do not** remove the needle from the skin when the plunger reaches the end.



Fig L

Slowly release your thumb up. This will allow the needle to move up into the clear needle guard and cover the entire needle (Fig. M).

Call your healthcare professional or pharmacist if you did not inject the full dose or the clear needle guard does not activate after injecting. **Do not** reuse a syringe in case of partial injection. **Do not** try to recap needle as it could lead to needle stick injury.



Fig M

e) If there is blood or liquid on the injection site, gently press a cotton ball or gauze on the skin.

Step 6: Throw away your Syringe

Throw away your used syringe in a sharps disposal container right away after use

Step 7: Record your Injection

To help you remember when and where to do your next injection, you should keep a record of the dates and injection sites used for your injections.



Fig N

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

PrIdacio[®] (pronounced)
< i-DAS-i-oh >
40 mg / 0.8 mL (50 mg / mL)
Adalimumab Injection
Sterile solution for Subcutaneous injection (vial)

Idacio is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humira[®]. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Read this carefully before you / your child start taking Idacio and each time you / your child get a refill. This leaflet is a summary and will not tell you / your child everything about this drug. Talk to your / your child's healthcare professional about your / your child's medical condition and treatment and ask if there is any new information about Idacio.

Serious Warnings and Precautions

Before starting, during and after treatment with Idacio, you / your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test. Any medicine can have side effects. Like all medicines that affect your / your child's immune system, Idacio can cause serious side effects. The possible serious side effects include:

- **Allergic reactions:** If you / your child develop a severe rash, swollen face or difficulty breathing while taking Idacio, call your / your child's doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab injection. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab injection is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab injection or other TNF-blockers. Some patients receiving adalimumab injection have developed types of cancer called non-melanoma skin cancer. Tell your / your child's doctor if you / your child have a bump or open sore that does not heal. People with more serious rheumatoid arthritis that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you / your child take Idacio, Idacio or other TNF- blockers, your / your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab injection, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you / your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your / your child's cheeks or arms that gets worse in the sun, call your / your child's doctor right away. Your / your child's doctor may decide to stop your / your child's treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab injection or other TNF-blockers. Signs that you / your child could be experiencing a problem affecting your / your child's nervous system include: numbness or tingling, problems with your / your child's vision, weakness in your / your child's legs, and dizziness.

- **Serious infections:** There have been rare cases where patients taking adalimumab injection or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), and very rare cases of hepatitis B infection relapse.
- **Blood problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, such as anemia (low red blood cells) or low platelets. If you / your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your / your child's doctor right away

What is Idacio used for?

Idacio treatment should be started and supervised by specialist physicians experienced in the diagnosis and treatment of polyarticular juvenile idiopathic arthritis (JIA), pediatric Crohn's disease (CD) or pediatric uveitis and familiar with the Idacio efficacy and safety profile.

Idacio is a medicine that is used in:

- patients 2 years of age and older who have polyarticular juvenile idiopathic arthritis, which is an inflammatory disease affecting one or more joints, with diagnosis typically occurring in children under the age of 16 years.
- children 13 to 17 years weighing ≥ 40 kg who have severe Crohn's disease or who have Crohn's disease which has not responded to other usual treatments. Crohn's disease is an inflammatory disease of the digestive tract.
- children with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.
- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed Idacio to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given Idacio. If you have ulcerative colitis or you / your child have Crohn's disease, you / your child will first be given other medicines. If you / your child do not respond well enough to these medicines, you / your child will be given Idacio to reduce the signs and symptoms of your / your child's disease.

How does Idacio work?

Idacio is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. Idacio binds to a specific protein called TNF- alpha (also known as tumor necrosis factor).

People with polyarticular juvenile idiopathic arthritis or Crohn's disease have too much TNF-alpha in their bodies. The extra TNF-alpha in your / your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your / your child's joints or digestive tract. By binding to TNF-alpha, Idacio decreases the inflammation process of these diseases.

Idacio helps reduce the signs and symptoms of polyarticular juvenile idiopathic arthritis (such as pain and swollen joints), may help improve your / your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your / your child's joints. In addition, Idacio helps reduce the signs and symptoms of pediatric Crohn's disease (such as abdominal pain and diarrhea). Idacio may also help normalize childhood growth and pubertal development, and improve the quality of life in children who have Crohn's disease (such as body image, functional and social skills, and emotional health). Idacio may help improve the work productivity and activity

impairment in caregivers of children with Crohn's disease. Idacio helps control uveitis by reducing the risk of inflammation and loss of vision in pediatric patients. Idacio, however, can also lower your / your child's body's ability to fight infections. Taking Idacio can make you / your child more prone to getting infections or make any infection you / your child have worse.

What are the ingredients in Idacio?

Medicinal ingredients: adalimumab injection

Non-medicinal ingredients: citric acid monohydrate, disodium phosphate dihydrate, mannitol, polysorbate-80, sodium chloride, sodium dihydrogen phosphate dihydrate, sodium hydroxide, trisodium citrate dihydrate and water for injection.

Idacio comes in the following dosage forms:

Idacio is available in a single-use, 1 mL vial containing 40 mg adalimumab injection in 0.8 mL sterile solution (50 mg/mL). All contents of the carton do not contain natural rubber latex.

Do not use Idacio if:

You / your child should not take Idacio if you / your child have:

- an allergy to any of the ingredients in Idacio (see **What are the ingredients in Idacio?** Section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

To help avoid side effects and ensure proper use, talk to your / your child's doctor or pharmacist before you / your child take Idacio. Talk about any health conditions or problems you / your child may have, including if:

- you / your child have or have had any kind of infection including an infection that is in only one place in your / your child's body (such as an open cut or sore), or an infection that is in your / your child's whole body (such as the flu). Having an infection could put you / your child at risk for serious side effects from Idacio. If you are unsure, ask your / your child's doctor.
- you / your child have a history of infections that keep coming back or other conditions that might increase your / your child's risk of infections, including fungal infections.
- you / your child have ever had tuberculosis, or if you / your child have been in close contact with someone who has had tuberculosis. If you / your child develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your / your child's doctor right away. Your / your child's doctor will need to examine you / your child for tuberculosis and perform a skin test.
- you / your child resided or travelled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, blastomycosis, or parasitic infections. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your / your child's body. If you / your child take Idacio these may become active or more severe. If you don't know if you / your child have lived in or travelled to an area where these infections are common, ask your / your child's doctor.
- you / your child have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-colored urine, vomiting, and abdominal pain. If you / your child experience any of these signs and symptoms, contact your / your child's doctor immediately. These symptoms may occur several months after starting therapy with Idacio.
- you / your child experience any numbness or tingling or have ever had a disease that affects your / your child's nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you / your child have or have had heart failure.
- you / your child are scheduled to have major surgery or dental procedures.

- you / your child are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting Idacio.
- you / your child are taking other medicines for your / your child's rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, psoriasis, or other conditions. You / your child can take other medicines provided your / your child's doctor has prescribed them or has told you / your child it is acceptable that you / your child take them while you / your child are taking Idacio. It is important that you tell your / your child's doctor about any other medicines you / your child are taking for other conditions (for example, high blood pressure medicine) before you / your child start taking Idacio.
- you / your child are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you / your child are pregnant or could become pregnant
- you / your child are breast-feeding or plan to breast-feed.

If you / your child are not sure or have any questions about any of this information, ask your / your child's doctor.

Other warnings you / your child should know about:

If you / your child received Idacio while pregnant, your / her baby may be at higher risk for getting an infection for up to approximately five months after the last dose of Idacio received during pregnancy. It is important that you / she tell your / her baby's doctors and other healthcare professionals about your / her Idacio use during pregnancy so they can decide when your / her baby should receive any vaccine.

Tell your / your child's healthcare professional about all the medicines you / your child take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Idacio:

You / your child should not take Idacio with:

- other TNF-blockers such as Enbrel[®], Remicade[®], Cimzia[®], or Simponi[®]
- abatacept (Orencia[®])
- anakinra (Kineret[®])

If you / your child have questions, ask your / your child's doctor.

How to take Idacio:

Idacio is administered by injection under the skin (by subcutaneous injection).

Usual dose:

Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:

- weighing 10 kg to less than 30 kg: the recommended dose of Idacio is 20 mg every other week.
- weighing 30 kg or more: the recommended dose of Idacio is 40 mg every other week.

For patients who require a full 40 mg dose of Idacio, a 40 mg Pen and 40 mg prefilled syringe are also available.

Children, 13 to 17 years of age weighing \geq 40 kg, with Crohn's disease:

- For children weighing \geq 40 kg, the recommended dose is 160 mg initially at Week 0 (given as four 40 mg injections in one day, or as two 40 mg injections per day for two consecutive days), followed by 80 mg at Week 2 (given as two 40 mg injections). At Week 4, you / your child will begin a maintenance dose of 20 mg every other week. Depending on

your / your child's response, the doctor may increase the dose to 40 mg every other week (given as one 40 mg injection). For the initial treatment or for an increase in dose to 40 mg, a 40 mg Pen and 40 mg prefilled syringe are also available.

Children, from 2 years of age with Uveitis:

- weighing less than 30 kg: the usual dose of Idacio is 20 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 40 mg to be administered one week prior to the start of the usual dose if your child is older than 6 years of age.
- weighing 30 kg or more: the usual dose of Idacio is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.

For the initial treatment or for an increase in dose to 40 mg, a 40 mg Pen and 40 mg prefilled syringe are also available.

Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

Adults with Crohn's Disease or Ulcerative Colitis:

- The recommended dose is 160 mg at Week 0, followed by 80 mg at Week 2 administered by subcutaneous injection. The first dose of 160 mg can be given in one day (four 40 mg injections) or split over two consecutive days (two 40 mg injections each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections in one day. The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

Adults with Hidradenitis Suppurativa:

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later administered by subcutaneous injection. The first dose of 160 mg at Week 0 can be given in one day (four 40 mg injections) or split over two consecutive days (two 40 mg injections). The second dose of 80 mg at Week 2 is given as two 40 mg injections in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

Adults with Psoriasis or Uveitis:

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose administered by subcutaneous injection. The first dose of 80 mg can be given as two 40 mg injections.

Overdose:

If you / your child accidentally inject Idacio more frequently than instructed, contact your / your child's doctor or local poison control centre right away.

Missed Dose:

If you / your child forget to give yourself/your child an injection, you / your child should inject the missed dose of Idacio as soon as you / your child remember. Then administer the next dose as you / your child would have on the originally scheduled date.

What are possible side effects from using Idacio?

These are not all the possible side effects you / your child may feel when taking Idacio. If you / your child experience any side effects not listed here, contact your / your child's healthcare professional. Please also see Warnings and Precautions.

Like all medicines, Idacio can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment. Tell your / your child's doctor immediately if you / your child experience any of the following:

- severe rash, hives or other signs of allergic reaction
- swollen face, hands, feet

- trouble breathing, swallowing
- sudden weight gain (this is possibly indicative of new or worsening heart failure)
- bruising or bleeding very easily, looking very pale; this could mean a blood problem such as low red blood cells (anemia) or low platelets.

Tell the doctor as soon as possible if you / your child notice any of the following:

- signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- feeling weak or tired
- coughing
- tingling
- numbness
- double vision
- arm or leg weakness
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus (this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection)
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your / your child's urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss

Serious side effects and what to do about them			
Symptom/effect	Talk with the doctor or pharmacist		Stop taking drug and call the doctor or pharmacist
	Only if severe	In all cases	
VERY COMMON (≥10 %) Injection site reaction		√	
COMMON (≥1 % and ≤10 %) Upper respiratory tract infections (including cold symptoms, such as sore throat and runny nose)		√	√
Headache	√		
Rash		√	
Nausea		√	
Appendicitis		√	√
Liver enzyme elevations		√	√
UNCOMMON (≥0.1 % and ≤1 %) Tuberculosis		√	√
Other serious infections		√	√
Nerve disorder (including symptoms such as numbness or tingling, problems with vision, weakness in arms or legs and dizziness)		√	√
Herpes simplex (cold sores)		√	√
Pneumonia (lung infection with symptoms such as cough, fever and chest pain)		√	√
Bronchopneumonia (lung infection with symptoms such as cough, fever and chest pain)		√	√
Streptococcal pharyngitis (throat infection with symptoms such as sore throat and fever)		√	√
Low white blood cell count		√	√

If you / your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your / your child's daily activities, talk to your / your child's healthcare professional.

General Advice About Prescription Medicines

Talk to your / your child's doctor or other healthcare provider if you / your child have any questions about this medicine or your / your child's condition. Medicines are sometimes prescribed for purposes other than those listed in a **PATIENT MEDICATION INFORMATION** leaflet. If you / your child have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you / your child information about this medicine that was written for health care professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at 1-877-821-7724.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffectcanada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 2 and 8°C (in a refrigerator) in the original carton until ready to use. **DO NOT FREEZE.** Protect from light. Refrigerated Idacio remain stable until the expiration date printed on the vial. Do not use beyond the expiration date.

If needed, the Idacio dose may be prepared ahead of time by withdrawing it from the vial and holding it in the syringe provided in the kit. The solution in the syringe may be held at room temperature for up to 3 hours.

Keep out of reach and sight of children.

If you want more information about Idacio:

- Talk to your / your child's healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website (<https://www.fresenius-kabi.com/en-ca>), or by calling 1-877-821-7724.

This leaflet was prepared by Fresenius Kabi Canada Ltd. 165 Galaxy Blvd, Suite 100, Toronto, ON M9W 0C8

Date revised: October 30, 2020

Idacio is trademark of Fresenius Kabi AG; Fresenius Kabi AG is a trademark of Fresenius SE.

Instructions for Use:

For your / your child's protection, it is important that you follow these instructions.

Step 1: Gather supplies and check for damages

- a) Remove the Idacio Vial Kit from the refrigerator.
- b) Check the expiration date on the side of the box. Do not use if the expiration date has passed.

- c) Leave the kit at room temperature for at least 30 minutes to allow the medicine to warm up. Injecting cold medicine may be painful (Fig. A).
Do not warm the kit any other way, such as in a microwave, hot water, or direct sunlight.



Fig. A

- d) Open the kit and take out all components and put them on a clean, dry, flat surface. Check components to make sure that the packaging and the content are not damaged (Fig. B).



Vial



Vial adapter

Fig. B



Needle



Syringe

Do not use if damaged.

- e) You will also need following supplies that are **not included** in the kit:

- A clean cotton ball or gauze, and
- A sharps container
- Alcohol pads

Open your sharps container so it is ready.

- f) Check your records for injection dates and injection sites to figure out the injection site for this session.

Step 2: Wash your hands

Wash your hands with soap, water and dry them well.
Gloves **do not** replace the need for washing hands.

Step 3: Prepare your vial

a) Check the label on the vial for Idacio and expiration date

Do not use the vial if:

- The name on the vial is not Idacio.
- The expiration date on the vial has passed.

b) Check the liquid to make sure that:

The liquid is clear, colorless, and free of particles.

Do not use the vial if the liquid is cloudy, colored or has particles or flakes in it.

c) Gently remove the yellow cap from the vial (Fig. C).



Fig. C

d) Wipe the entire vial top with an alcohol pad and throw the pad away. **Do not** touch the top of the vial after cleaning.

e) Peel off the paper from the vial adapter packaging without taking the vial adaptor out of its packaging (Fig. D).

Do not touch the vial adapter.



Fig. D

f) With the vial adapter still in its packaging, push the vial adapter onto the vial top until it snaps in place (Fig. E).



Fig. E

g) Hold the vial and lift the packaging off. To ensure the adapter remains on top of the vial, hold the packaging by the outer rim (Fig. F).



Fig. F

Step 4: Prepare Syringe

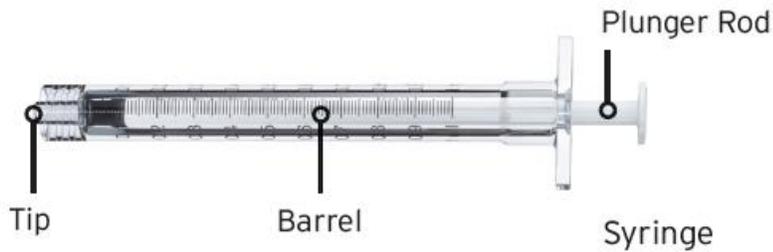


Fig. G

a) Peel open the syringe packaging and grab the syringe by the barrel (Fig. H). **Do not** touch the syringe tip.



Fig. H

b) Hold the vial adapter, insert the syringe tip into it and screw to connect (Fig. I).



Fig. I

- c) Turn the vial upside down so it is vertical with the syringe still attached.
- d) Keep the vial and syringe vertical and slowly pull the prescribed dose.



Fig. J

If the plunger rod is pulled completely out, throw away the syringe. **Do not** try to reinsert it and use a new kit.

e) Slowly push the plunger rod all the way in to push the medicine back into the vial. This is to remove any air gaps or bubbles. Again, slowly pull the plunger out to the prescribed dose and stop. If you still see air gaps or bubbles at the tip of the syringe, repeat this step until air gaps or bubbles are gone (Fig. K). **Do not** shake the syringe.

Do not use the syringe if there is a large amount of air in the syringe.

f) Turn over the vial and syringe, firmly hold the vial adapter and unscrew the syringe from the vial adapter (Fig. L).



Fig. K



Fig. L

g) Place the syringe on a clean, flat surface.

Do not touch the syringe tip.

Do not throw the vial away.

Step 5: Prepare Needle

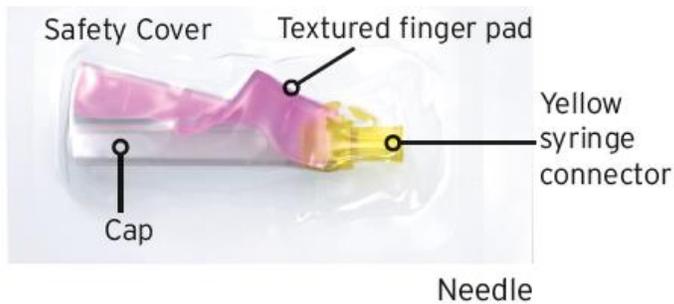


Fig. M

a) Peel open the needle packaging to uncover the yellow syringe connector (Fig. N).

Do not take the needle out of its packaging.

Do not touch the yellow connector.

Fig. N



b) Insert the syringe tip into the yellow syringe connector and screw to connect.

Fig. O



c) Pull the needle packaging off. **Do not** remove the clear needle cap (Fig. O).

d) Pull back the pink needle safety cover toward the syringe (Fig. P). **Do not** detach the pink needle safety cover from the yellow connector.

Fig. P



e) Place the syringe on a clean, flat surface

Step 6: Prepare Injection

a) Choose an injection site on (Fig. Q):

- Top of the thighs or
- Lower stomach area (inject at least 5 centimeters away from the belly button). Choose a different injection site (at least 2.5 centimeters away from the previous injection site) each time to reduce redness, irritation or other skin problems.

Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where there are stretch marks.



b) Clean the injection site with an alcohol pad and throw the pad away. **Do not** blow on or touch the injection site after cleaning.

Fig. Q

c) Remove the clear needle cap by pulling it straight off and throw it away (Fig. R).

Do not try to put the needle cap back on the needle.

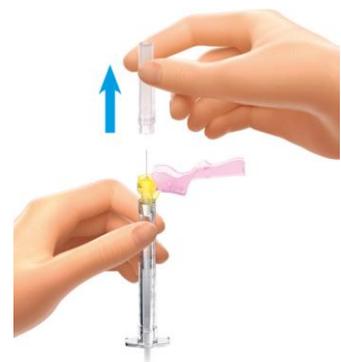


Fig. R

d) Hold the syringe like a pencil with the pink needle safety cover pointing up (Fig S)



Step 7: Give Injection

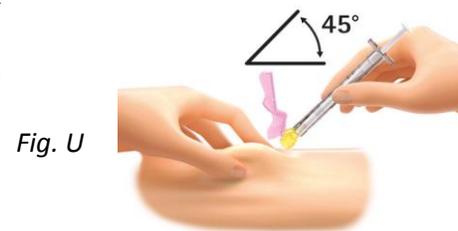
a) With the other hand, gently pinch a fold of cleaned skin and maintain it (Fig. T).

Do not touch where you aim to inject.



b) With a quick, short motion, push the needle into the skin at an angle of 45° (Fig. U).

Note: With experience, you will find the angle (between 45° and 90°) that is most comfortable for you and the child.

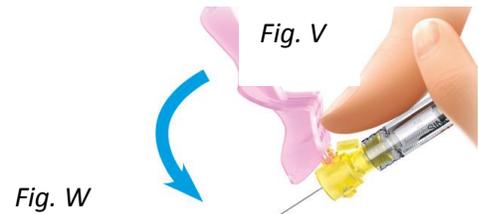


c) Gently push the white plunger rod all the way down until the syringe is empty (Fig. V).



d) Remove the needle from the skin, being careful to pull it out at the same angle that it was inserted.

Then release the pinched skin



e) Center your thumb or forefinger on the textured finger pad and push the safety cover forward over the needle until you hear or feel it locks (Fig X).



f) The needle is now covered and is safe. It can now be thrown away in the sharps container (Fig. X).
Call your healthcare professional if you did not inject the full dose.

g) If there is blood or liquid on the injection site, gently press a clean cotton ball or gauze on the skin for 10 seconds.
Do not rub the injection site.

Step 8: Record injection and dispose components

a) Now that you have completed your injection, update your record with:

- the injection site
- the date
- any issue you had
- the lot number (on vial label).

b) Throw away the used syringe with the protected needle and the vial with attached vial adapter into a sharps container.

Keep your sharps disposal container out of the reach of children.

Do not keep any unused medicine.

Do not throw away the syringe or the vial in your household trash.

If you do not have a sharps disposal container, you may use a household container that is:

- Made of a heavy-duty plastic;
- Can be closed with a tight-fitting, puncture-resistant lid; that will keep sharps from coming out,
- Upright and stable during use,
- Leak-resistant and
- Properly labeled to warn of hazardous waste inside the container.

c) When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container. **Do not** recycle your used sharps disposal container.