

Ketorolac Kabi

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ketorolac Kabi?

KETOROLAC KABI contains the active ingredient ketorolac trometamol. KETOROLAC KABI is used to relieve pain and reduce inflammation (swelling and soreness) that may occur following surgery. For more information, see Section [1. Why am I using KETOROLAC KABI?](#) in the full CMI.

2. What should I know before I use Ketorolac Kabi?

Do not use KETOROLAC KABI if you are pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed. Do not use KETOROLAC KABI if you are allergic to ketorolac trometamol, aspirin or any other NSAID medicine, or any of the ingredients listed at the end of this leaflet. **Talk to your doctor if you have any other medical conditions or take any other medicines.** For more information, see Section [2. What should I know before I use KETOROLAC KABI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KETOROLAC KABI and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Ketorolac Kabi?

KETOROLAC KABI is given as an injection, into a muscle by a doctor or trained nurse. The usual dose for healthy adults is 10 mg to 30 mg every 4 to 6 hours, up to a maximum daily dose of 90 mg. More information can be found in Section [4. How do I use KETOROLAC KABI?](#) in the full CMI.

5. What should I know while using Ketorolac Kabi?

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| Things you should do | <ul style="list-style-type: none">Call your doctor straight away if you become pregnant while receiving KETOROLAC KABI.Tell your doctor if you get an infection soon after receiving KETOROLAC KABI. |
| Things you should not do | <ul style="list-style-type: none">Do not receive KETOROLAC KABI for longer than 5 days. Prolonged use may increase the occurrence of side effects |
| Driving or using machines | <ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how KETOROLAC KABI affects you.As with other NSAID medicines, KETOROLAC KABI may cause dizziness or light-headedness in some people. |
| Drinking alcohol | <ul style="list-style-type: none">Tell your doctor if you drink alcohol.If you drink alcohol, dizziness or light-headedness may be worse. |
| Looking after your medicine | <ul style="list-style-type: none">KETOROLAC KABI will be stored in the pharmacy or on the hospital ward. It is kept in a cool dry place where the temperature stays below 25°C. It should be protected from light. |

For more information, see Section [5. What should I know while using KETOROLAC KABI?](#) in the full CMI.

6. Are there any side effects?

Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects: vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions or bloody diarrhoea, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, asthma, wheezing, shortness of breath, sudden or severe itching, skin rash or hives, fainting, seizures or fits, pain or tightness in the chest, or flu-like symptoms with a rash on the face then an extended rash with a high temperature and enlarged lymph nodes. Tell your doctor immediately if you notice any of the following serious side effects: severe dizziness, spinning sensation, severe or persistent headache, abnormal vision, bleeding or bruising more easily than normal, reddish or purplish blotches under the skin, severe pain or tenderness in any part of the stomach or back, unusual weight gain, swelling of ankles or legs. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Ketorolac Kabi

Active ingredient: *ketorolac trometamol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ketorolac Kabi. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ketorolac Kabi.**

Where to find information in this leaflet:

- [1. Why am I using Ketorolac Kabi?](#)
- [2. What should I know before I use Ketorolac Kabi?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Ketorolac Kabi?](#)
- [5. What should I know while using Ketorolac Kabi?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Ketorolac Kabi?

KETOROLAC KABI contains the active ingredient **ketorolac trometamol**. KETOROLAC KABI belongs to a family of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs).

KETOROLAC KABI is used to relieve pain and reduce inflammation (swelling and soreness) that may occur following surgery. Although KETOROLAC KABI can relieve the symptoms of pain and inflammation, it will not cure your condition.

Your doctor may have prescribed KETOROLAC KABI for another purpose.

2. What should I know before I use Ketorolac Kabi?

Warnings

Do not use Ketorolac Kabi if:

- you are allergic to ketorolac trometamol, aspirin or any other NSAID medicine, or any of the ingredients listed at the end of this leaflet. Many medicines used to treat headache, period pain and other aches and pains contain aspirin or NSAID medicines. If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist. If you are allergic to aspirin or NSAID medicines and use KETOROLAC KABI, these symptoms may be severe. Symptoms of an allergic reaction to these medicines may include:
 - asthma, wheezing or shortness of breath
 - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing

- hives, itching or skin rash
- fainting

Always check the ingredients to make sure you can use this medicine.

- you are pregnant or intend to become pregnant
- you are breastfeeding or intend to breastfeed
- you have kidney disease
- you have severe liver disease
- you have severe heart failure
- you have recently had or are about to have heart bypass surgery
- you have a peptic ulcer (stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before
- you have had any bleeding disorders
- you have asthma
- you suffer dehydration
- you have nasal polyps syndrome, angioedema or bronchospasm (breathing difficulties)
- you have a history of Stevens-Johnsons Syndrome (a rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals)
- you are receiving the following medicines:
 - other NSAID medicines
 - probenecid, a medicine used to treat gout
 - lithium, a medicine used to treat some types of depression
 - oxpentifylline, a medicine used to treat certain blood disorders

Do not give KETOROLAC KABI to a child under 16 years of age.

The safety and effectiveness in children under 16 have not been established.

If you are not sure if you should be given KETOROLAC KABI, contact your doctor.

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - heartburn, indigestion, stomach ulcers or other stomach problems
 - kidney or liver disease
 - heart failure
 - high blood pressure or heart problems
 - swelling of the ankles or feet
 - inflammatory bowel disease, such as Crohn's disease

- take any medicines for any other condition
- you have any allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes
- you currently have an infection. KETOROLAC KABI may hide some of the signs of an infection (e.g. pain, fever) and may make you think that the infection is not serious or that you are better.
- you plan to have surgery
- you have ever smoked or been a heavy alcohol drinker

If you have not told your doctor about any of the above, tell them before you are given KETOROLAC KABI.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use KETOROLAC KABI if you are pregnant or intend to become pregnant.

KETOROLAC KABI may affect your developing baby if you are given it during pregnancy. If it is necessary for you to be given KETOROLAC KABI, your doctor will discuss the risks and benefits of receiving it during pregnancy.

KETOROLAC KABI may impair fertility and is not recommended in women attempting to conceive.

Do not use KETOROLAC KABI if you are breast-feeding or intend to breast-feed.

KETOROLAC KABI passes into breast milk. The effect on the baby is not known.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Ketorolac Kabi and affect how it works. These include:

- aspirin, salicylates or other NSAID medicines (such as ibuprofen or naproxen)
- warfarin, a medicine used to stop blood clots
- probenecid, a medicine used to treat gout
- oxpentifylline, a medicine used to treat certain blood disorders
- lithium, a medicine used to treat some types of depression
- selective serotonin reuptake inhibitors (SSRIs), medicines used to treat depression (such as fluoxetine, paroxetine or citalopram)
- thiothixene, a medicine used to treat psychosis

- diuretics, also called fluid or water tablets
- phenytoin, a medicine used to treat epilepsy
- carbamazepine, a medicine used to treat epilepsy
- methotrexate, a medicine used to treat arthritis and some cancers
- heparin, a medicine used to treat blood disorders
- medicines used to treat high blood pressure, including ACE inhibitors, angiotensin receptor antagonists and beta-blockers.
- certain antibiotics called aminoglycosides

You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor will advise you.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ketorolac Kabi.

4. How do I use Ketorolac Kabi?

How KETOROLAC KABI is given

- KETOROLAC KABI is given as an injection, into a muscle by a doctor or trained nurse.
- The injection should not be injected directly into the veins (intravenously).
- Your doctor will decide what dose of KETOROLAC KABI you will receive. This depends on your condition.
- The usual dose for healthy adults is 10 mg to 30 mg every 4 to 6 hours, up to a maximum daily dose of 90 mg.
- If you are over 65 years old or have reduced kidney function, your doctor may prescribe a lower dose.

When KETOROLAC KABI is given

- KETOROLAC KABI injection is given every 4 to 6 hours as required, up to a maximum daily dose of 90 mg

How long KETOROLAC KABI is given for

- **Do not receive KETOROLAC KABI for longer than 5 days.** Prolonged use may increase the occurrence of side effects.

If you use too much Ketorolac Kabi

If you receive too much KETOROLAC KABI, you may have pain or tenderness in the stomach, stomach upset including nausea (feeling sick), vomiting, heartburn, indigestion or cramps. If you think that you have used too much KETOROLAC KABI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

5. What should I know while using Ketorolac Kabi?

Call your doctor straight away if you:

- become pregnant while receiving KETOROLAC KABI
- get an infection soon after receiving KETOROLAC KABI.
KETOROLAC KABI may hide some of the signs of an infection and may make you think, mistakenly, that the infection is not serious or that you are better.
Signs of an infection may include fever, pain, swelling and redness.

Remind any doctor, dentist or pharmacist you visit that you are using KETOROLAC KABI.

If you are going to have surgery, tell your doctor you are being given KETOROLAC KABI.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ketorolac Kabi affects you.

As with other NSAID medicines, KETOROLAC KABI may cause dizziness or light-headedness in some people. Make sure you know how you react to KETOROLAC KABI before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

- KETOROLAC KABI will be stored in the pharmacy or on the hospital ward. It is kept in a cool dry place where the temperature stays below 25°C. It should be protected from light.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Other side effects not listed here may occur in some people. Tell your doctor if you notice anything else that is making you feel unwell.

Less serious side effects

| Less serious side effects | What to do |
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| <p>Gastrointestinal or gut related:</p> <ul style="list-style-type: none">• stomach upset including• nausea (feeling sick), heartburn, indigestion• pain in the stomach or wind• diarrhoea <p>Head related:</p> <ul style="list-style-type: none">• dizziness• drowsiness• headache• dry mouth• feeling extremely thirsty <p>Skin related:</p> <ul style="list-style-type: none">• skin rash or hives• sweating <p>Muscle related:</p> <ul style="list-style-type: none">• aching muscles, muscle tenderness or weakness, not caused by exercise <p>Injection related:</p> <ul style="list-style-type: none">• pain at site of injection <p>Urinary or bladder related:</p> <ul style="list-style-type: none">• passing more or less urine than normal | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Head related:</p> <ul style="list-style-type: none">• severe dizziness, spinning• sensation• severe or persistent headache• abnormal vision <p>Bleeding related:</p> <ul style="list-style-type: none">• bleeding or bruising more easily than normal, reddish or purplish blotches under the skin <p>Pain related:</p> <ul style="list-style-type: none">• severe pain or tenderness in any part of the stomach or back <p>Other:</p> <ul style="list-style-type: none">• unusual weight gain, swelling of ankles or legs | <p>Tell your doctor immediately if you notice any of these side effects. You may need urgent medical attention. These are serious side effects. Serious side effects are rare.</p> |

Very serious side effects

| Very serious side effects | What to do |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Gastrointestinal or gut related: <ul style="list-style-type: none">vomiting blood or material that looks like coffee groundsbleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea | Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. You may need urgent medical attention or hospitalization. These very serious side effects are rare. |
| Allergic reaction related: <ul style="list-style-type: none">swelling of the face, lips or tongue which may cause difficulty in swallowing or breathingasthma, wheezing, shortness of breathsudden or severe itching, skin rash or hivesfainting, seizures or fitspain or tightness in the chestflu-like symptoms with a rash on the face then an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. | |

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving KETOROLAC KABI.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is only available with a doctor's prescription.
KETOROLAC KABI is not additive.

What Ketorolac Kabi contains

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|-----------------------------------------------------|---------------------------------------------------------------------------------------------|
| Active ingredient (main ingredient) | Each 30 mg/mL KETOROLAC KABI injection contains 30 mg of ketorolac trometamol |
| Other ingredients (inactive ingredients) | ethanol sodium chloride sodium hydroxide or hydrochloric acid water for injections |

Potential allergens

KETOROLAC KABI does not contain sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Ketorolac Kabi looks like

KETOROLAC KABI is a clear to slightly yellow solution supplied in a 1 mL glass vial. It comes in a pack of 5 vials.

KETOROLAC KABI 30 mg/mL (AUST R 275273)

Who distributes Ketorolac Kabi

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Australia
Telephone: (02) 9391 5555

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