

# **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 being given lonolyte?

lonolyte contains the active ingredients sodium chloride, sodium acetate trihydrate, potassium chloride and magnesium chloride hexahydrate. Ionolyte is a sterile infusion solution used as a source of water and electrolytes (salts). It is used when there is an acid imbalance in the body.

For more information, see Section 1. Why am I being given lonolyte? in the full CMI.

# 2. What should I know before I am given Ionolyte?

Do not use if you have ever had an allergic reaction to lonolyte or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given lonolyte? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with lonolyte and affect how it works. These include medicines used:

- to treat digestive tract ulcers
- to increase the urine volume
- to control blood pressure and treat heart failure
- to prevent organ rejection
- to relax muscles
- to treat pain

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

# 4. How is lonolyte given?

lonolyte will be given to you in hospital by a doctor or nurse. You will receive your medicine by intravenous infusion (infusion into a vein). The amount and rate at which the infusion is given depends on your condition. Your doctor will decide on the correct dose for you to receive.

More instructions can be found in Section 4. How is lonolyte given? in the full CMI.

## 5. What should I know while being given lonolyte?

Things you should do	<ul> <li>Remind any doctor, dentist, or pharmacist of the medications you are currently taking, especially those listed in Section 3.</li> <li>Tell your doctor if you are pregnant.</li> </ul>	
Things not to do	You must not be given lonolyte if you have any of the conditions listed under Section 2. What should I know before I am given lonolyte?	
Driving or using machines	Ionolyte has no effect on the ability to be able to drive or use machines.	

For more information, see Section 5. What should I know while being given lonolyte? in the full CMI.

# 6. Are there any side effects?

All medicines have side effects. Sometimes they are serious, most of the time they are not. You will be monitored by a doctor or nurse during treatment. Please tell your doctor or nurse immediately if you notice any side effects.

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.

# **Ionolyte**®

**Active ingredient(s):** sodium chloride, sodium acetate trihydrate, potassium chloride and magnesium chloride hexahydrate

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using lonolyte. 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 lonolyte.

#### Where to find information in this leaflet:

- 1. Why am I being given lonolyte?
- 2. What should I know before I am given lonolyte?
- 3. What if I am taking other medicines?
- 4. How is Ionolyte given?
- 5. What should I know while being given lonolyte?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I being given Ionolyte?

Ionolyte contains the active ingredient sodium chloride, sodium acetate trihydrate, potassium chloride and magnesium chloride hexahydrate.

Ionolyte is used as a source of water and electrolytes (salts). It is also used

Ionolyte is used for mild metabolic acidosis as a source of water and electrolytes.

# 2. What should I know before being given lonolyte?

#### Warnings

#### Do not use lonolyte if:

- you are allergic to sodium chloride, sodium acetate trihydrate, potassium chloride and magnesium chloride hexahydrate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You have too much fluid in your body, and you have been told that you have a condition known as hyperhydration
- You have been told that you have pulmonary edema, where too much fluid is in your lungs
- You have been told that you have a congestive heart failure (a condition in which your heart cannot pump enough blood to other organs of your body)
- You have severely impaired kidney function
- You have decreased acidity of the blood caused by a metabolic disorder
- You have high potassium levels in your blood

#### Check with your doctor if you:

- have any other medical conditions such as:
  - heart failure
  - severe heart rate disorders
  - impaired kidney function
  - severe electrolyte abnormalities (e.g too high blood levels of potassium, sodium, magnesium or chloride)
  - high blood pressure
  - eclampsia (complication of pregnancy mainly manifested by high blood pressure and significant amounts of protein in the urine)
  - aldosteronism (syndrome of high blood pressure and low blood potassium levels caused by an excess of the natural hormone aldosterone)
  - treatments or conditions associated with sodium retention (e.g. corticoids/steroids)
  - potassium-sparing diuretics (used to increase the urine volume)
  - severe potassium deficiency
  - heart disease where you take heavy doses of digitalis
  - myasthenia gravis (a disease involving severe muscle weakness)
  - an operation where a muscle relaxant was used (neuromuscular block)
- take any medicines for any other condition

Tell your doctor if any of the warnings listed above applies to you or when this has been the case in the past.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The safety of the product in pregnant and breast-feeding women has not been investigated. Your doctor will only give lonolyte after having weighed the benefits versus the potential risk to the baby.

# 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 lonolyte and affect how it works.

Ionolyte is not recommended if you are taking/using:

- corticoids/steroids (for the treatment of digestive tract ulcers) as these are associated with retention of sodium and water (with fluid accumulation in tissues and high blood pressure)
- potassium-sparing diuretics (used to increase the urine volume, such as amiloride, spironolactone, triamterene, given alone or in combination)
- angiotensin converting enzyme inhibitors (ACE inhibitors) and angiotensin II receptor antagonists (medicines that are mainly used for controlling blood pressure, treating heart failure)
- tacrolimus and cyclosporine (medicine used to prevent organ rejection)
- muscle relaxants
- salicylates (used to ease pains and reduce fever)
- lithium (anti-psychotic)
- alkaline drugs like sympathomimetics (such as amphetamine).

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

# 4. How do is lonolyte given?

#### How much is given

The amount and rate at which the infusion is given depends on your condition. Your doctor will decide on the correct dose for you to receive.

#### How is Ionolyte given

Ionolyte will be given to you in hospital by a doctor or nurse. You will receive your medicine by intravenous infusion (infusion into a vein).

#### If you are given too much lonolyte

It is very unlikely that you will receive more infusion than you should because this medicine will be given to you by your doctor or nurse who will monitor you during the treatment. However, tell your doctor or nurse if you have any concerns.

In the event of accidental overdose, treatment will be stopped, and you will be observed for signs and symptoms related to the drug. Therapeutic removal of excessive fluid might be necessary.

# 5. What should I know while being given lonolyte?

### Things you should do

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

If you are going to have surgery, tell the surgeon or anesthetist that you have been given this medicine.

It may affect other medicines used during surgery.

If you become pregnant after being given this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you have been given this medicine. It may interfere with the results of some tests.

# **Driving or using machines**

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

lonolyte has no effect on the ability to drive or use machines.

#### Looking after your medicine

Ionolyte will be stored in the pharmacy or kept on the ward. Ionolyte should be stored below 30°C and not be frozen.

# 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.

You will be monitored by your doctor or nurse during treatment with this medicine. If any of these side effects appear, the treatment will be stopped.

#### Less serious side effects

Less serious side effects	What to do
Very common (occurring in more than 1 in 10 patients):	Speak to your doctor if you
Hyperhydration (too much fluid in your body) and heart failure in patients with heart disorder or pulmonary oedema (fluid accumulation in the lungs)	have any of these less serious side effects and they worry you.
Common (occurring in more than 1	
in 100 patients, but less than 1 in 10	
patients	
Large volumes of this solution may	
lead to dilution of components of	
the blood and decrease in the	
haematocrit (proportion of blood	

volume that is occupied by red blood cells)

Other side effects include:

• Fluid accumulation in tissues (oedema)

• Fever

• Infection at the site of injection, local pain or reaction

• Vein irritation, venous thrombosis (formation of a clot) or phlebitis (inflammation of the vein) extending from the site of injection

• Extravasation (fluid leakage from the vein)

#### Serious side effects

Serious side effects	What to do
<ul> <li>Rash, itching or hives on the skin</li> <li>Swelling of the face, lips, tongue, or other part of the body.</li> <li>Shortness of breath, wheezing, or trouble breathing.</li> </ul>	Call your doctor or nurse straight away.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

### 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

# 7. Product details

This medicine is only available with a doctor's prescription.

## What Ionolyte contains

Active ingredient	Sodium chloride
(main ingredient)	Sodium acetate trihydrate Potassium chloride Magnesium chloride hexahydrate
Other ingredients (inactive ingredients)	Sodium hydroxide Hydrochloric acid Water for injections
Potential allergens	None

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

#### What Ionolyte looks like

lonolyte is a sterile, clear and colourless solution for intravenous infusion that comes in 500 mL and 1000 mL freeflex® bags.

Ionolyte solution for infusion 500 mL in packs of 20 bags: (Aust R 211732).

Ionolyte solution for infusion 1000 mL in packs of 10 bags: (AUST R 213304).

#### Who distributes lonolyte

Supplied in Australia by: Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080 Australia

Tel: (02) 9391 5555

® = Registered Trademark

This leaflet was prepared in Aug 2023.