

Ionolyte[®]

Sodium chloride, sodium acetate trihydrate, potassium chloride and magnesium chloride hexahydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ionolyte. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using this product against the benefits they expect it will have for you.

Please read this leaflet carefully. If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet. You may need to read it again.

What is Ionolyte used for

Ionolyte is a sterile infusion solution used as a source of water and electrolytes (salts). It is also used when there is an acid imbalance in the body.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Ionolyte is not addictive.

Before you are given Ionolyte

When you must not be given Ionolyte

You must NOT be given this product if:

- 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
- You are allergic (hypersensitive) to any of the active and inactive ingredients of this product

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given Ionolyte

Your doctor may need to take special precautions and will decide whether you can receive Ionolyte if:

- You suffer from heart failure
- You suffer from severe heart rate disorders
- You suffer from impaired kidney function
- You have severe electrolyte abnormalities (e.g. too high

blood levels of potassium, sodium, magnesium or chloride)

- You have high blood pressure
- You suffer from eclampsia (complication of pregnancy mainly manifested by high blood pressure and significant amounts of protein in the urine)
- you suffer from aldosteronism (syndrome of high blood pressure and low blood potassium levels caused by an excess of the natural hormone aldosterone)
- you have other treatments or conditions associated with sodium retention (e.g. corticoids/steroids)
- you are taking potassium-sparing diuretics (used to increase the urine volume)
- you have severe potassium deficiency
- you have taken heavy doses of digitalis (a medicine used for treatment of heart diseases)
- you suffer from myasthenia gravis (a disease involving severe muscle weakness)
- you recently had an operation where a muscle relaxant was used (neuromuscular block)
- larger volumes of this solution are to be used

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription

from your pharmacy, supermarket or health food shop.

lonolyte 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).

Using lonolyte with food and drink

lonolyte is not known to have any negative effect when given at the same time as food and drink.

Pregnancy and breast-feeding

Please tell your doctor if you are pregnant, you think you are pregnant, planning to become pregnant or if you are breast-feeding.

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.

Driving and using machines

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

How lonolyte is given

How much will you be 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.

If you take too much (overdose)

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.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia) or 0800 764 766 (New Zealand).

Side Effects

Like all medicines lonolyte can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in

this leaflet, please tell your doctor or nursing staff immediately:

Very common (occurring in more than 1 in 10 patients):

- hyperhydration (too much fluid in your body) and heart failure in patients with heart disorder or pulmonary oedema (fluid accumulation in the lungs)

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)

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.

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell. If this occurs, the use of this product should be stopped immediately.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. Discuss

any concerns you have with your doctor.

Storage

Ionolyte should be stored below 30°C and not be frozen. As with any medicine, Ionolyte should be stored out of the reach of children. Do not use the product after the expiry date shown on the label or the container is damaged.

Disposal

The hospital staff will dispose of any unused Ionolyte.

Product Description

What Ionolyte looks like

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

Ingredients

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

Ionolyte also contains the inactive ingredients: sodium hydroxide, hydrochloric acid and water for injections.

Ionolyte does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Ionolyte does not contain any preservative.

Ionolyte comes in 2 different sizes of plastic (**freeflex**[®]) bag. They can be identified by the following AUST R numbers:

Australian Registration Number

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

Further Information

More detailed information is available from your doctor or pharmacist. Therefore, if you have any concerns about the information or about Ionolyte please ask your doctor or pharmacist.

Sponsor

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

Supplied in New Zealand by:
Fesenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland
New Zealand
Freecall: 0800 144 892

® = Registered Trademark

Date of Information

This leaflet was prepared in Mar 2016.