Package leaflet: Information for the user

Ionolyte Solution for Infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ionolyte is and what it is used for

Ionolyte is a solution for infusion.

Ionolyte is used for the treatment of:
- extracellular dehydration (water loss)
- hypovolaemia (sudden drop in volume of circulating blood)
- mild metabolic acidosis (increased acid in the blood caused by a metabolic disorder).

2. What you need to know before you are given Ionolyte

Do not use Ionolyte
- if you are allergic to Sodium acetate trihydrate, Sodium chloride, Potassium chloride, Magnesium chloride hexahydrate or any of the other ingredients of this medicine (listed in section 6).

You should not receive Ionolyte if you have
- hyperhydration (too much fluid in the body), especially in cases of pulmonary oedema (fluid accumulation in the lungs) and congestive cardiac failure (your heart cannot pump enough blood througout the body)
- severely impaired kidney function
- metabolic alkalosis (decreased acidity of the blood caused by a metabolic disorder)
- hyperkalaemia (too high blood levels of potassium)

Your doctor will check these.

Special care will be taken with Ionolyte if

- you have heart failure
- you have severe heart rate disorders
- you have **i**mpaired 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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ionolyte.

Children and adolescents

No special warnings and precautions**.**

Other medicines and Ionolyte

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Ionolyte is not recommended if you are taking/using:

- corticoids/steroids and carbenoxolone (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 relaxant***s***
- salicylates (used to ease pains and reduce fever)
- lithium (anti-depressant)
- alkaline drugs like sympathomimetics (such as amphetamine).

Ionolyte with food and drink

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine .

Ionolyte can be used safely during pregnancy and breast-feeding as long as the electrolyte and fluid balance is controlled.

When another medicinal product is added to Ionolyte, the nature of the drug and its use during pregnancy and breast-feeding have to be considered separately. Your doctor will discuss this with you.

Driving and using machines
Ionolyte has no effect on the ability to drive or use machines.

3. How to use Ionolyte

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).
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 are given more Ionolyte than you should
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.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

Very common (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 (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.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly:

For UK – via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcar or search for MHRA Yellow Card in the Google Play or Apple App Store

For Ireland – via the HPRA Pharmacovigilance, website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ionolyte

Do not refrigerate or freeze.

Keep this medicine out of the sight and reach of children.

The product should be used immediately after opening.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ionolyte contains

- The active substances are:

	500 ml	**1000 ml**
Sodium acetate trihydrate	2.32 g	4.63 g
Sodium chloride	3.01 g	6.02 g
Potassium chloride	0.15 g	0.30 g
Magnesium chloride hexahydrate	0.15 g	0.30 g

Electrolytes:

Na^+	137.0 mmol/l
K^+	4.0 mmol/l
Mg^{++}	1.5 mmol/l
Cl^-	110.0 mmol/l
CH_3COO^-	34.0 mmol/l

Theoretical osmolarity:	286.5 mOsm/l
Titrable acidity:	< 2.5 mmol NaOH/l
pH:	6.9 – 7.9

- The other ingredients are:
  Water for injections

Sodium hydroxide (for pH-adjustment)
Hydrochloric acid (for pH-adjustment)

What Ionolyte looks like and contents of the pack
Ionolyte is a clear and colourless solution packed in a flexible sealed plastic container known as a **free***flex*® bag or in a plastic bottle known as a KabiPac®.

The solution is available in 500 ml or 1000 ml presentation.

Polyolefine bag (**free***flex*®) with overwrap: 20 x 500 ml, 10 x 1000 ml
LDPE bottle (KabiPac®): 10 x 500 ml, 20 x 500 ml, 10 x 1000 ml

Not all pack sizes may be marketed**.**

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
For UK:
Fresenius Kabi Limited
Cestrian Court, Eastgate Way,
Manor Park, Runcorn,
Cheshire, WA7 1NT
UK

For IE:
Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1,
61352 Bad Homburg
v.d.Höhe
Germany

Manufacturer:
Fresenius Kabi Deutschland GmbH
Freseniusstraße
61169 Friedberg
Germany

Or

Fresenius Kabi France
6, rue du rempart
F - 27400 Louviers

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium	Ionolyte, oplossing voor infusie
Bulgaria	Ionolyte инфузионен разтвор
Croatia	Ionolyte, otopina za infuziju
Cyprus	Ionolyte, διάλυμα για έγχυση
Czech Republic	Isolyte, Infuzní roztok
France	Ionoven, solution pour perfusion

Greece	Ionolyte, διάλυμα για έγχυση
Hungary	Isolyte, oldatos infúzió
Ireland	Ionolyte Solution for infusion
Italy	Ionolyte
Malta	Ionolyte Solution for infusion
Netherlands	Ionolyte, oplossing voor infusie
Norway	Ionolyte infusjonsvæske, oppløsning
Poland	Venolyte
Portugal	Ionolyte, solução para perfusão
Romania	Ionolyte solu ie perfuzabil
Slovakia	Isolyte, infúzny roztok
Slovenia	Ionolyte raztopina za infundiranje
Spain	IONOLYTE solución para perfusión
United Kingdom	Ionolyte Solution for infusion

This leaflet was last revised in July 2020

The following information is intended for healthcare professionals only:

Posology

Adults and paediatric patients

The dose and rate of administration depends on age, body weight, clinical and biological conditions of the patient (including acid-base balance) and the concomitant therapy.

Recommended dosage:
The maximum daily dose corresponds to the fluid and electrolyte needs of the patient. To temporary restore blood volume 3 to 5 times the volume of the lost blood is required.

Typical recommended dosages are:
For adults, the elderly and adolescents (age 12 years and above): 500 ml to 3 litres/24 hours.
For infants, toddlers and children (from 28 days to 11 years of age): 20 ml/kg to 100 ml/kg/24 hours.

Administration rate:
In continuous treatment outside acute fluid losses the infusion rate is usually 40 ml/kg/24 hours in adults.
In pediatric patients the infusion rate is 5 ml/kg/hour in average but the value varies with the age: 6-8 ml/kg/hour for infants, 4-6 ml/kg/hour for toddlers, and 2-4 ml/kg/hour for school children.

Method of administration
For intravenous use.