

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ringer's Solution for Infusion

Active substances: sodium chloride, potassium chloride and calcium chloride dihydrate

Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Ringer's Solution for Infusion is and what it is used for
2. What you need to know before you are given Ringer's Solution for Infusion
3. How you will be given Ringer's Solution for Infusion
4. Possible side effects
5. How to store Ringer's Solution for Infusion
6. Contents of the pack and other information

1. What Ringer's Solution for Infusion is and what it is used for

Ringer's Solution for Infusion is a solution of the following substances in water:

- sodium chloride
- potassium chloride
- calcium chloride dihydrate
- Ringer's Solution for Infusion is used to treat a loss of body water (dehydration) and chemicals (e.g. by heavy sweating, kidney disorders)

2. What you need to know before you are given Ringer's Solution for Infusion

Do NOT receive Ringer's Solution for Infusion if you are suffering from any of the following Conditions

- Preterm newborn infants and term newborn infants (≤ 28 days of age): Your child must not receive a certain antibiotic called ceftriaxone as a drip into a vein at the same time with this medicine
- when there is too much fluid in the spaces around the cells of the body (extracellular hyperhydration)
- when there is a larger volume of blood in the blood vessels than there should be (hypervolaemia)
- severe kidney failure (when your kidneys do not work well and you require dialysis)
- uncompensated heart failure. This is heart failure that is not adequately treated and causes symptoms such as:
 - shortness of breath
 - swelling of the ankles
- when there is too much fluid in the body caused by too many salts in the blood (hypertonic dehydration)
- higher levels of potassium in the blood than normal (hyperkalaemia)
- higher levels of sodium in the blood than normal (hypernatraemia)
- higher levels of calcium in the blood than normal (hypercalcaemia)

- higher levels of chloride in the blood than normal (hyperchloraemia)
- severe high blood pressure (hypertension)
- build up of fluid under the skin, affecting all parts of the body (general oedema)
- liver disease that causes fluid to build up within the abdomen (ascitic cirrhosis)
- if you are taking cardiac glycosides (cardiotonics) used to treat heart failure, such as digitalis or digoxin. (see also “Other Medicines and Ringer’s Solution for Infusion”)

Warnings and precautions

Talk to your doctor or nurse if you have or have had any of the following medical conditions:

- respiratory failure (lung disease) (special monitoring may be required in the above conditions)
- any type of heart disease or impaired heart function
- impaired kidney function
- high blood pressure (hypertension)
- build up of fluid under the skin, particularly around the ankles (peripheral oedema)
- build up of fluid in the lungs (pulmonary oedema)
- high blood pressure during pregnancy (pre- eclampsia)
- a disease that causes high levels of a hormone called aldosterone (aldosteronism)
- any other condition associated with sodium retention (when the body retains too much sodium), such as treatment with steroids (see also below “Other medicines and Ringer’s Solution for Infusion”).
- if you have problems with the fluid levels in your brain (for example, because of meningitis, bleeding in the skull or brain injury)
- if you have a condition that could cause high level of vasopressin, a hormone regulating fluid in your body, such as
 - a sudden and serious illness or injury
 - you have had surgery
 - brain disease
 - you are taking certain medicines

These conditions may increase the risk of low levels of sodium in your blood, which can lead to headache, nausea, seizures, lethargy, coma and swelling in the brain.

People who are at higher risk of brain swelling are:

- children
- women (particularly if you are of a fertile age)
- if you have a condition where the glands in the body are not making enough of some hormones (adrenocortical insufficiency)
- a loss of water from the body (acute dehydration, e.g. from vomiting or diarrhoea)
- extensive tissue damage (can occur in severe burns)
- diseases associated with high levels of vitamin D (e.g. sarcoidosis, a disease affecting the skin and internal organs)
- diseases associated with kidney stones
- ceftriaxone, an antibiotic, must not be mixed with or given at the same time as any solutions with calcium in, when given to you through the vein. This medicine contains calcium. If you are older than 28 days, you may be given ceftriaxone and a solution with calcium, one after the other, as long as your doctor takes action to avoid medicines reacting with each other. If you or your child suffer from low blood volume your doctor will avoid giving you or your child calcium and ceftriaxone sequentially heart failure.

When you are given this infusion, your doctor will take blood and urine samples and monitor:

- the amount of fluid in your body
- your vital signs
- the amount of chemicals such as sodium, potassium, calcium and chlorides in your blood (your plasma electrolytes)

Although Ringer's Solution for Infusion contains potassium and calcium, it does not contain enough to:

- maintain levels of these chemicals
- treat very low blood plasma levels of potassium (severe potassium deficiency) or calcium (severe calcium deficiency).

Once your dehydration has been treated using Ringer's Solution for Infusion, your doctor will give you a different infusion to provide you with enough potassium and calcium. Your doctor will take into account if you are receiving parenteral nutrition (nutrition given by infusion into a vein). If you are given Ringer's Solution for Infusion for a long time, you will be given an extra source of nutrients.

Calcium chloride can be harmful if injected into the body tissues. Therefore, the Ringer's Solution for Infusion must not be given by injecting it into a muscle (intramuscular injection). Also, your doctor will make every effort to avoid the escape of the solution into the tissues surrounding the vein.

Ringer's Solution for Infusion must not be given through the same needle as a blood transfusion. This can damage the red blood cells or cause them to clump together.

Other medicines and Ringer's Solution for Infusion

Tell your doctor or nurse if you are taking or have recently taken any other medicines. It is particularly important that you inform your doctor if you are taking:

- ceftriaxone (an antibiotic), when given intravenously (see Warnings and precautions)
- cardiac glycosides (cardiotonics) such as digitalis or digoxin, used to treat heart failure as they must not be used with Ringer's Solution for Infusion (see also section "Do not receive Ringer's Solution for Infusion if you are suffering from..."). The effects of these drugs can be increased by calcium. This can lead to life threatening changes to the heart rhythm

The following medicines can cause the body to store up sodium and water, leading to tissue swelling and high blood pressure:

- corticosteroids (anti-inflammatory medicines)
- carbenoxolone (an anti-inflammatory medicine used to treat stomach ulcers)

The following medicines can increase the concentration of potassium in the blood. This effect can be life-threatening. A rise in the blood potassium levels is more likely to occur if you have kidney disease.

- potassium-sparing diuretics (certain water tablets, e.g. amiloride, spironolactone, triamterene)
(Note that these medicines may be included in combination medicinal products)
- angiotensin converting enzyme (ACE) inhibitors (used to treat high blood pressure)
- angiotensin II receptor antagonists (used to treat high blood pressure)
- tacrolimus (used to prevent rejection of a transplant and to treat some skin diseases)
- cyclosporin (used to prevent rejection of a transplant)

Some medicines can increase the risk of side effects due to low levels of sodium in blood. These medicines may include:

- water tablets (diuretics)
- medicines for pain and /or inflammation (also known as NSAIDs)
- antipsychotics
- medicines used to treat depression (selective serotonin reuptake inhibitors)
- medicines that produce morphine-like effects (opioids)
- certain medicines used to treat epilepsy (antiepileptics)
- hormone called oxytocin (causes uterus to contract)
- certain medicines used to treat cancer (chemotherapy).
- cholesterol medicine
- anti-diabetic medicine

Other medicines that can affect or be affected by Ringer's Solution for Infusion include:

- thiazide diuretics such as hydrochlorothiazide or chlortalidone
- vitamin D

Ringer's Solution for Infusion with food and drink

You should ask your doctor about what you can eat or drink.

Pregnancy, breast-feeding and fertility

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

Ringer's Solution for Infusion can be used safely during pregnancy or breast-feeding as long as the electrolyte and fluid balance is controlled and monitored by your doctor. Your doctor will take special caution if you are taking oxytocin during labour.

Calcium can reach your unborn baby through the placenta and, after birth, through the breast milk. Your doctor will monitor the levels of chemicals in your blood and the amount of fluid in your body.

However, if another medicine is to be added to your solution for infusion during pregnancy particularly during labour or breast-feeding you should:

- consult your doctor
- read the Package Leaflet of the medicine that is to be added.

Driving and using machines

Ringer's Solution for Infusion does not affect your ability to drive or use machines.

3. How to use Ringer's Solution for Infusion

Ringer's Solution for Infusion will be given to you by a doctor or nurse. Your doctor will decide on how much you need and when it is to be given. This will depend on your age, weight, and condition and the reason for treatment. The amount you are given may also be affected by other treatments you are receiving.

You should NOT be given Ringer's Solution for Infusion if there are particles floating in the solution or if the pack is damaged in any way.

Ringer's Solution for Infusion will usually be given to you through a plastic tube attached to a needle

in a vein. Usually a vein in your arm is used to give you the infusion. However, your doctor may use another method to give you the medicine.

When you are given Ringer's Solution for Infusion, your doctor will perform blood tests to monitor your:

- blood levels of sodium, potassium, calcium and chloride
- your fluid levels

Any unused solution should be thrown away. You should NOT be given an infusion of Ringer's Solution for Infusion from a bag that has been partly used.

If you receive more Ringer's Solution for Infusion than you should

If you are given too much Ringer's Solution for Infusion (over-infusion), or you are given your infusion too quickly, this may lead to the following symptoms:

- water and/or sodium (salt) overload with build up of liquid in the tissues (oedema) causing swelling
- pins and needles in the arms and legs (paresthesia)
- muscle weakness
- an inability to move (paralysis)
- an irregular heartbeat (cardiac arrhythmias)
- heart block (a very slow heartbeat)
- cardiac arrest (the heart stops beating; a life- threatening situation)
- confusion
- a decreased appetite (anorexia)
- feeling sick (nausea)
- vomiting
- constipation
- abdominal pain
- mental disturbances such as irritability or depression
- drinking lots of water (polydipsia)
- producing more urine than normal (polyuria)
- kidney disease due to build up of calcium in the kidneys (nephrocalcinosis)
- kidney stones
- coma (unconsciousness)
- chalky taste
- redness (hot flushes)
- dilatation of the blood vessels in the skin (peripheral vasodilatation)
- acidification of the blood (acidosis) leading to tiredness, confusion, lethargy and increased breathing rate

If you develop any of these symptoms you must inform your doctor immediately. Your infusion will be stopped and you will be given treatment depending on the symptoms.

If a medicine has been added to your Ringer's Solution for Infusion before over-infusion occurs, that medicine may also cause symptoms. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

Stop receiving your Ringer's Solution for Infusion

Your doctor will decide when to stop giving you this infusion.

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

4. Possible side effects

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

The side effects are listed according to their frequencies.

Very common (occurring in more than 1 of every 10 patients)

- changes in the concentrations of the chemicals in the blood (electrolyte disturbances)

If you suffer from heart disease or fluid in the lungs (pulmonary oedema):

- too much fluid in the body (hyperhydration)
- heart failure

Other

- reactions due to the administration technique:
 - fever (febrile response)
 - infection at the site of infusion
 - local pain or reaction (redness or swelling at the site of infusion)
 - irritation and inflammation of the vein into which the solution is infused (phlebitis). This can cause redness, pain or burning and swelling along the path of the vein into which the solution is infused.
 - the formation of a blood clot (venous thrombosis) at the site of infusion, which causes pain, swelling or redness in the area of the clot
 - escape of the infusion solution into the tissues around the vein (extravasation). This can damage the tissues and cause scarring.
- low levels of sodium in the blood (hyponatraemia)
- swelling of the brain which may cause brain injury (cerebral-oedema)

If a medicine has been added to the solution for infusion, the added medicine may also cause side effects. These side effects will depend on the medicine that has been added. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed below. By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom:

Via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Ireland:

HPRA Pharmacovigilance,
Earlsfort Terrace,
IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.

Website: www.hpra.ie;
E-mail: medsafety@hpra.ie.

Malta:

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Ringer's Solution for Infusion

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

This medicinal product does not require any special temperature storage conditions

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

Do not use this medicine if you notice particles floating in the solution or if the unit is damaged in any way.

6. Contents of the pack and other information

What Ringer's Solution for Infusion contains

The active substances are:

- sodium chloride: 8.60 g per litre
 - potassium chloride: 0.30 g per litre
 - calcium chloride dihydrate: 0.33 g per litre
 - water for injections
 - sodium hydroxide
- The other ingredients are:

What Ringer's Solution for Infusion looks like and contents of the pack

Ringer's Solution for Infusion is a clear solution, free from visible particles.

It is supplied in a polyolefin/polyamide plastic bags (Viaflo). Each bag is wrapped in a sealed, protective, outer plastic overpouch.

The bag sizes are:

- 500 ml
- 1000 ml

The bags are supplied in cartons. Each carton contains one of the following quantities:

- 1 bag of 500 ml
- 20 bags of 500 ml
- 1 bag of 1000 ml
- 10 or 12 bags of 1000 ml

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:

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For information about Ringer's Solution for Infusion or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: +44 (0)1635 206345

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**The following information is intended for healthcare professionals only:
Handling and Preparation**

Use only if the solution is clear, without visible particles and if the container is undamaged.

Administer immediately following the insertion of infusion set.

Do not remove unit from overwrap until ready for use.

The inner bag maintains the sterility of the product.

Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.

Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration. Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.

The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

Additives may be introduced before infusion or during infusion through the re-sealable medication port.

When additive is used, verify isotonicity prior to parenteral administration. Thorough and careful aseptic mixing of any additive is mandatory. Solutions containing additives should be used immediately and not stored.

Adding medication or using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In case of adverse reaction, infusion must be stopped immediately.

Discard after single use.

Discard any unused portion.

Do not reconnect partially used bags.

1. Opening

- a. Remove the Viaflo container from the overpouch just before use.
- b. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution, as sterility may be impaired.
- c. Check the solution for limpidity and absence of foreign matters. If solution is not clear or contains foreign matters, discard the solution.

2. Preparation for administration

Use sterile material for preparation and administration.

- a. Suspend container from eyelet support.
- b. Remove plastic protector from outlet port at bottom of container:
 - grip the small wing on the neck of the port with one hand,
 - grip the large wing on the cap with the other hand and twist,
 - the cap will pop off.
- c. Use an aseptic method to set up the infusion.
- d. Attach administration set. Refer to complete directions accompanying set for connection, priming of the set and administration of the solution.

3. Techniques for injection of additive medications

Warning: Additives may be incompatible (see paragraph 5 "Incompatibilities of additive medications" below).

To add medication before administration

- a. Disinfect medication port.
- b. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture re-sealable medication port and inject.
- c. Mix solution and medication thoroughly. For high-density medication such as potassium chloride, tap the ports gently while ports are upright and mix.

Caution: Do not store bags containing added medications.

To add medication during administration

- a. Close clamp on the set
- b. Disinfect medication port.
- c. Using syringe with 19 gauge (1.10 mm) to 22 gauge (0.70 mm) needle, puncture re-sealable medication port and inject.
- d. Remove container from IV pole and/or turn to an upright position.
- e. Evacuate both ports by tapping gently while the container is in an upright position.
- f. Mix solution and medication thoroughly.
- g. Return container to in use position, re-open the clamp and continue administration

4. In-use shelf life (Additives)

The chemical and physical stability of any additive at the pH of the Ringer's solution in the Viaflo container should be established prior to use.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution has taken place in controlled and validated aseptic conditions.

5. Incompatibilities of additive medications

As with all parenteral solutions, before adding medications, compatibility of these additives with the solution in Viaflo container must be assessed.

It is the responsibility of the physician to judge the incompatibility of an additive medication with the Ringer's Solution for Infusion by checking for eventual colour change and/or eventual appearance of precipitate, insoluble complexes or crystals. The Instructions for Use of the medicinal product to be added must be consulted.

Before adding a drug, verify it is soluble and stable in water at the pH of Ringer's Solution for Infusion (pH: 5.0 to 7.5).

Calcium salts have been reported to be incompatible with a wide range of drugs. Complexes may form resulting in the formation of a precipitate.

- Concomitant treatment with ceftriaxone and Ringer's Solution for Infusion is contraindicated in preterm newborn infants and term newborn infants (≤ 28 days of age), even if separate infusion lines are used.
- In patients of any age ceftriaxone must not be mixed or administered simultaneously with any calcium-containing IV solutions even via different infusion lines or infusion sites.
- If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid.

- Sequential infusions of ceftriaxone and calcium-containing products must be avoided in case of hypovolaemia

As a guidance, the following medications are incompatible with the Ringer's Solution (non-exhaustive listing):

- Amphotericin B
- Cortisone
- Erythromycin lactobionate
- Etamivan
- Ethyl alcohol
- Thiopental sodium
- Disodium edetate

Those additives known to be incompatible should not be used.

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