

Approved Patient information Leaflet for Ringer-Lactate Solution Fresenius

SCHEDULING STATUS **S3**

Ringer-Lactate Solution Fresenius

Solution for infusion

Each 1 000 ml contains:

Calcium chloride hexahydrate	0,4 g
Or Calcium chloride dihydrate	0,268 g
Potassium chloride	0,4 g
Sodium chloride	6,0 g
Sodium lactate	3,25 g

Sugar free.

Read all of this leaflet carefully before you are given Ringer-Lactate Solution Fresenius

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.

What is in this leaflet

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

1. What Ringer-Lactate Solution Fresenius is and what it is used for

Ringer-Lactate Solution Fresenius is a solution of the following substances in water: calcium, chloride, lactate, potassium and sodium.

It is used to treat a loss of body water (dehydration), which occurs after burns, trauma, severe diarrhoea or an operation.

It is also used to treat loss of blood volumes, which occurs after bleeding (haemorrhage).

2. What you need to know before you are given Ringer-Lactate Solution Fresenius

Do not receive Ringer-Lactate Solution Fresenius:

- if you are hypersensitive (allergic) to calcium, chloride, lactate, potassium, sodium or any of the other ingredients of Ringer-Lactate Solution Fresenius (listed in section 6)
- if you have kidney failure (when your kidneys do not work well), or you produce abnormally small amounts of urine (oliguria) or if your kidneys are not producing any urine (anuria)
- if you suffer from a medical condition characterised by major shock and renal failure after a crushing injury to skeletal muscle (crush syndrome)
- if you experience a life-threatening reaction after receiving a blood transfusion (severe haemolytic reactions)
- if you have a condition in which your adrenal glands do not produce adequate amounts of steroid hormones, primarily cortisol (adrenocortical insufficiency)
- if you have higher levels of potassium in the blood than normal (hyperkalaemia)
- if you have a low urine output after an operation (oliguria)
- if you have higher levels of sodium in your blood than normal (hypernatraemia)
- if there is too much water (extracellular hyperhydration) or blood (hypervolaemia) in your body than there should be
- if you have heart failure
- if you have higher levels of calcium in your blood than normal (hypercalcaemia)
- if you have a condition called metabolic alkalosis, which occurs when your blood becomes overly alkaline

- if you have a liver disease that causes fluid to build up within your stomach area (ascitic cirrhosis)
- if you have abnormally high levels of acid, caused by your metabolism in your blood (severe metabolic acidosis)
- if you have an impairment to metabolise lactate, connected with high levels of lactate in your blood (hyperlactataemia)
- if you are taking medicine used to treat heart failure, such as digoxin (see Other medicines and Ringer-Lactate Solution Fresenius)

Preterm newborn infants and full term newborn infants (≤ 28 days of age):

Your child must not receive ceftriaxone (an antibiotic) as a drip into a vein at the same time with Ringer-Lactate Solution Fresenius.

Warnings and precautions

Tell your doctor or health care provider before being given the infusion:

- if you experience any signs or symptoms of a hypersensitive (allergic) reaction (see Possible side effects)
- if you or your child are receiving treatment with ceftriaxone (see Other medicines and Ringer-Lactate Solution Fresenius)
- if you have a heart disease
- if you are dehydrated (insufficient water in your body)
- if you have acute deficiency of water in your body or extensive tissue destruction, as occurs with severe burns
- if you have a disease associated with high levels of vitamin D in your blood (sarcoidosis)
- if you have too high levels of chloride in your blood
- if your kidneys are not functioning normal
- if you have heart or lung failure, as you need to be closely monitored
- if you have high levels antidiuretic hormone (ADH – causing your body to retain too much water) due to

- acute illness, pain, post-operative stress, infections, burns and central nervous system (CNS) diseases
- heart-, liver- and kidney diseases
- if you have cerebral oedema (characterised by headache, nausea, seizures, lack of energy and vomiting)
- if you are a woman of childbearing potential with the following conditions: meningitis, acute bleeding inside your skull or brain, bruises of the brain and brain swelling
- if you have excess water in your body (hyperhydration)
- if you have a hormonal disorder that leads to high blood pressure (aldosteronism)
- if you have high blood pressure (hypertension)
- if you have a pregnancy complication characterised by high blood pressure (preeclampsia)
- if you have abnormally high levels of bases in your blood, caused by your metabolism (severe metabolic alkalosis)
- if you have high blood sugar (diabetes)
- if you receive Ringer-Lactate Solution Fresenius for a long term, you should also receive a convenient nutritive supply.

Other medicines and Ringer-Lactate Solution Fresenius

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking or receiving any of the following medicines:

- ceftriaxone (an antibiotic, used to treat certain bacterial infections)
- chlorpropamide (used to treat diabetes mellitus type 2)
- clofibrate (used to treat high cholesterol)
- carbamazepine and oxcarbazepine (used to treat epilepsy, fits)
- vincristine, cyclophosphamide, ifosfamide (used to treat cancer)

- selective serotonin reuptake inhibitors (antidepressants, used to treat depression)
- narcotics (used for pain relief)
- anti-inflammatory medicine (used to treat inflammation)
- desmopressin or vasopressin (used to treat diabetes insipidus)
- oxytocin (used to induce labour or control bleeding after childbirth)
- terlipressin (used to treat bleeding of the enlarged blood vessels in the oesophagus (tube connecting the throat (pharynx) and the stomach))
- thiazide diuretics (used to treat high blood pressure)
- corticosteroids (used to treat allergic conditions)
- amiloride, spironolactone or triamterene (used to increase water loss in patients with high blood pressure)
- angiotensin-converting enzyme (ACE) inhibitors (e.g. benazepril, zofenopril, perindopril,trandolapril, captopril, enalapril used to treat high blood pressure)
- tacrolimus or ciclosporin (immunosuppressant medicine, used to prevent rejection after organ transplant)
- digoxin (used to treat heart rhythm disorders or heart failure)
- vitamin D supplements
- bisphosphonates or fluorides (used for the treatment of brittle bone disease)
- fluoroquinolones or tetracyclines (antibiotics used to treat certain bacterial infections)
- salicylates (e.g. aspirin used to relieve pain and inflammation)
- barbiturates (used to treat anxiety, insomnia or seizure disorders)
- lithium (used to treat mood disorders)
- ephedrine (used to treat breathing problems)
- pseudoephedrine (used to relieve nasal congestion caused by colds, allergies or hay fever)
- dexamphetamine sulphate (used to treat attention deficit hyperactivity disorder (ADHD) and narcolepsy (sleepiness))
- fenfluramine (used to treat seizures associated with Dravet syndrome)

Pregnancy and breastfeeding

Safety in pregnancy and breastfeeding has not been established.

Your doctor will carefully monitor your sodium levels during labour especially if he/she is also giving you oxytocin (see Other medicines and Ringer-Lactate Solution Fresenius).

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving Ringer-Lactate Solution Fresenius.

Driving and using machines

Ringer-Lactate Solution Fresenius has no influence on the ability to drive a vehicle or use machines.

Ringer-Lactate Solution Fresenius contains sodium

Each ml Ringer-Lactate Solution Fresenius contains 0,0021 g sodium, equivalent to 2,1 g sodium per 1 000 ml solution. Your doctor will take this into account if you are on a sodium-controlled diet.

3. How Ringer-Lactate Solution Fresenius will be given

Ringer-Lactate Solution Fresenius is administered into the vein.

You will not be expected to give yourself Ringer-Lactate Solution Fresenius. It will be given to you by a person who is qualified to do so.

Your doctor will determine your dose, the rate at which Ringer-Lactate Solution Fresenius is dripped into your veins and for how long this should continue. The dose will depend on your age, body mass, medical condition and the laboratory results. If you have an impression that the effect of Ringer-Lactate Solution Fresenius is too strong or too weak, talk to you doctor or pharmacist.

Your doctor will monitor the calcium, chloride, lactate, potassium and sodium in your blood before you are being treated and during treatment with Ringer-Lactate Solution Fresenius, especially if

you are on medicines as mentioned (see Other medicines and Ringer-Lactate Solution Fresenius).

If you receive more Ringer-Lactate Solution Fresenius than you should

Since a health care provider will administer Ringer-Lactate Solution Fresenius, he/she will control the dosage. However, in the event of overdosage your doctor will manage the symptoms of overdosage.

If you miss a dose of Ringer-Lactate Solution Fresenius

Since a health care provider will administer Ringer-Lactate Solution Fresenius, it is unlikely that a dose will be missed.

4. Possible side effects

Ringer-Lactate Solution Fresenius can have side effects.

Not all side effects reported for Ringer-Lactate Solution Fresenius are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving Ringer-Lactate Solution Fresenius, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving Ringer-Lactate Solution Fresenius and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Ringer-Lactate Solution Fresenius.

Tell your doctor immediately if you notice any of the following:

Frequency unknown:

- Decreased ability to think, headaches, nausea and poor balance. These symptoms could be an indication of low sodium levels in your blood (hyponatraemia).
- Neurological symptoms typically occur with very low levels of plasma sodium. When sodium levels in the blood become very low, water enters the brain cells and causes them to swell. This results in increased pressure in the skull and causes hyponatraemic encephalopathy and is a medical emergency.

These are all serious side effects. You may need urgent medical attention.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Ringer-Lactate Solution Fresenius.

Health care providers are asked to report any suspected Adverse Drug Reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicines regulatory authority in the country where the product is marketed.

5. How to store Ringer-Lactate Solution Fresenius

- Store at or below 25 °C. Protect from light.
- Discard after single use.
- Discard any unused portion.

- Do not reconnect partially used bags.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Ringer-Lactate Solution Fresenius contains:

The active substances are calcium chloride hexahydrate or calcium chloride dihydrate, potassium chloride, sodium chloride and sodium lactate.

The other ingredient is water for injection.

What Ringer-Lactate Solution Fresenius looks like and contents of the pack:

Clear colourless solution in water for injection.

30 or 40 x 200 ml in **freeflex**[®] or PVC bags

10, 18 or 20 x 500 ml in **freeflex**[®] or PVC bags

12 x 1 000 ml in **freeflex**[®] or PVC bags

4 x 3 000 ml in PVC bags.

Not all container types and pack sizes may be marketed.

Holder of Certificate of Registration:

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