Patient Information Leaflet for Human Medicines

SCHEDULING STATUS

S3

RINGER LACTATE INFUSION B. BRAUN

Active substance: Sodium chloride, Sodium lactate, Potassium chloride and Calcium chloride dihydrate.

Read all of this leaflet carefully before you start are given RINGER LACTATE INFUSION B. BRAUN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- RINGER LACTATE INFUSION B. BRAUN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1: What RINGER LACTATE INFUSION B. BRAUN is and what it is used for
2: What you need to know before you use RINGER LACTATE INFUSION B. BRAUN
3: How to use RINGER LACTATE INFUSION B. BRAUN
4: Possible side effects
5: How to store RINGER LACTATE INFUSION B. BRAUN
6: Contents of the pack and other information

1: What RINGER LACTATE INFUSION B. BRAUN is and what it is used for

RINGER LACTATE INFUSION B. BRAUN is a solution for supply of fluid and salts to the body. It is supplied to you through a vein drip (an infusion). Its salt composition is similar to that of human blood.

Reduced liquid part of the blood volume resulting from burns, trauma, severe diarrhoea and surgery.

Reduced blood volumes resulting from abnormal flow of blood.

2: What you need to know before you use RINGER LACTATE INFUSION B. BRAUN

Do not use RINGER LACTATE INFUSION B. BRAUN if you have

- kidney failure
- muscle damage
- severe damage of red blood cells
- adrenal gland insufficiency
- high potassium levels
- low urine output after surgery
- high levels of sodium in blood.

Do not use RINGER LACTATE INFUSION B. BRAUN**.** If your hypersensitive to any of ingredients.

Warnings and Precautions

When given this medicine, patients who are acutely ill, with pain, postoperative stress, infections, burns, diseases of the nervous system, heart, liver or kidney, and patients who are on medicines

working like vasopressin (a hormone which regulates the amount of body fluids), are at particular risk of developing an abnormally low level of sodium in the blood (acute hyponatraemia) which can lead to a life-threatening swelling of the brain (hyponatraemic encephalopathy, brain oedema).

Women of childbearing potential and patients with serious brain conditions such as an infection of the membranes surrounding the brain (meningitis) or brain injury (intracranial bleeding, cerebral contusion) are at particular risk of the severe and life-threatening brain swelling caused by an abnormally low level of sodium in the blood.

Your doctor will exercise particular caution if you have

- lost water while retaining the salts
- too high blood levels of potassium, sodium, calcium or chloride
- abnormally high levels of bases in the blood caused by your metabolism (severe metabolic alkalosis)
- failure of your heart, liver, kidneys or lungs
- excess water in your body (peripheral oedema, extracellular hyperhydration)
- a condition where you are retaining sodium, such as high blood pressure,
- toxaemia of pregnancy (see “Pregnancy and breast-feeding”), too high levels of aldosterone in your body, treatment with cortisone
- a condition where you are retaining potassium, e.g. acute deficiency of
- water in your body, extensive tissue destruction as occurs with severe burns
- a disease associated with high levels of vitamin D in your blood such as Sarcoidosis
- kidney stones or a history of them.

If you have constantly low blood sodium levels your doctor will take special care to give you this solution slowly. This will prevent possible brain damages (osmotic demyelinisation syndrome).

Children

Children are at particular risk of the severe and life-threatening brain swelling caused by an abnormally low level of sodium in the blood.

Your doctor will take special care of your child aged less than 3 months if he/she receives this solution.

Use as vehicle solution

Please note: If this solution is used as vehicle solution the safety information of the additive provided by the respective manufacturer has to be taken into account.

While you receive this solution the following parameters will be checked to ensure that these are normal:

- your blood salt and lactate levels
- your acid-base balance
- your fluid balance.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before taking or using any medicine.

Pregnancy

If you are pregnant, please inform your doctor. Your doctor will administer this solution to you only if he thinks it is necessary.

Your doctor will exercise particular caution if you have toxaemia of pregnancy. This is a condition of the third trimester when the patient has the following symptoms:

- high blood pressure
- swelling of body tissues
- protein in the urine.

Breast-feeding

Calcium is excreted in human milk, but at therapeutic doses of RINGER LACTATE INFUSION B. BRAUN no effects on the breastfed newborns/infants are anticipated. Therefore RINGER LACTATE INFUSION B. BRAUN can be used during breast-feeding.

Driving and using machines

RINGER LACTATE INFUSION B. BRAUN has no influence on the ability to drive and use machines.

3: How to use RINGER LACTATE INFUSION B. BRAUN

Do not share medicines prescribed for you with any other Person.

RINGER LACTATE INFUSION B. BRAUN will be given to you by a doctor or a nurse.

Your doctor or nurse will decide the right dose of RINGER LACTATE INFUSION B. BRAUN depending on your fluid and electrolyte requirements.

Use a new solution each time. Discard the unused portion.

If you take more RINGER LACTATE INFUSION B. BRAUN than you should.

An overdose may lead to hyperhydration (excess fluid in the body), which will be followed by

- increased skin tension
- congestion in your veins
- swelling of body tissues
- water on the lungs or in your brain
- disorders of your fluid, salt and acid base balance,
- high salt levels in your blood.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4: POSSIBLE SIDE EFFECTS

Like all medicines, Compound Sodium Lactate can cause side effects, although not everybody gets them.

Frequency not known (cannot be estimated from the available data)

Hospital-acquired abnormally low blood sodium levels (hyponatraemia)

Brain swelling (brain oedema) due to abnormally low blood sodium levels (hyponatraemic encephalopathy). This may cause irreversible brain damage and death. The symptoms include: headache, feeling sick (nausea), vomiting, seizures, tiredness and lack of energy

Reporting of side effects

If you get side effects. Talk to your doctor, or pharmacist or nurse. You can also report side effects to SAHPRA via 6.04 Adverse Drug Reaction. Reporting Form found online under SAHPRAs 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 INFUSION B. BRAUN**.**

5: How to store RINGER LACTATE INFUSION B. BRAUN

Your doctor or pharmacist is responsible for storing this medicine. They are also responsible for disposing of any unused medicine correctly.

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

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

Store at or below 25 °C.

This medicinal product is for single use only. After administration, the container and any remaining solution are to be discarded.

The solution should be inspected visually prior to use. No special requirements for disposal.Only to be used if the solution is clear, colourless and the container and its closure do not show visible signs of damage.

Do not reconnect partially used containers.

6: Contents of the pack and other information

What RINGER LACTATE INFUSION B. BRAUN contains

The active substance 1000 mL of the solution for injection contains:

Sodium chloride	6,00 g
Sodium lactate solution	3,2 g
Potassium chloride	0,40 g
Calcium chloride dihydrate	0,27 g

Electrolyte concentrations:

Sodium	131 mmol/l
Potassium	5,4 mmol/l
Calcium	1,8 mmol/l
Chloride	112 mmol/l
Lactate	28 mmol/l

The other ingredient is: Water for injections

Theoretical osmolarity:	277 mOsm/l
Titration acidity:	< 1 mmol/l
pH:	5,0 – 7,0

What RINGER LACTATE INFUSION B. BRAUN looks like and contents the pack

A clear, colourless to slightly straw-coloured liquid.

A polyvinylchloride plastic bag in a polyethylene overwrap which is slightly opaque presented in the following sizes: 200 mL & 1 000 mL.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

B. Braun Medical (Pty) Ltd

253 Aintree Road

North Riding

Hoogland Ext 41

Randburg

Gauteng, South Africa, 2194.

This leaflet was revised in:

28 May 2021

Registration number

32/24/0130