Approved Patient Information Leaflet for BALSOL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

BALSOL solution for infusion

Sodium chloride, potassium chloride, magnesium chloride hexahydrate, sodium bicarbonate

Sugar free.

Read all of this leaflet carefully before you receive BALSOL:

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

What is in this leaflet:

1. What BALSOL is and what it is used for
2. What you need to know before you receive BALSOL
3. How BALSOL will be administered to you
4. Possible side effects
5. How to store BALSOL
6. Contents of the pack and other information

1. What BALSOL is and what it is used for

BALSOL contains a combination of electrolytes in the form of a sterile intravenous infusion.

BALSOL is used by your doctor to provide essential electrolytes and water if your body has been subjected to injury, for example if you have lost blood, during or after surgery, or if you have lost a lot of fluids or if your body fluids have become too acidic.

2. What you need to know before you receive BALSOL

BALSOL should not be given to you if:

- You are hypersensitive (allergic) to sodium chloride, potassium chloride, magnesium chloride hexahydrate, sodium bicarbonate or any of the other ingredients of BALSOL (listed in section 6).
- You have too much fluid in your body (a condition known as hyperhydration).
- You have been told that you have oedema where too much fluid accumulates in your body.
- You have decreased acidity of the blood caused by a metabolic disorder.
- You have been told that you have congestive heart failure (a condition in which your heart cannot pump enough blood to other organs in your body).
- You have severely impaired kidney function.
- You have any blood abnormalities such as high levels of sodium, low levels of calcium, potassium or chloride, or your blood is less acidic than usual (your doctor will need to check this).

Warnings and precautions:

Take special care if:

- You have heart failure, respiratory failure, severe heart rate disorders, impaired kidney function, or high blood pressure.
- You recently had an operation, have infection or extensive tissue damage (as can occur after severe burns).
- You suffer from pre-eclampsia (a complication during pregnancy causing high blood pressure).
- 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 severe electrolyte abnormalities (e.g. too high blood levels of potassium, sodium, magnesium or chloride; or low levels of sodium).
- 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.

Your doctor or nurse may want to regularly check your fluid balance, electrolyte and blood acid levels during the course of treatment with BALSOL.

Other medicines and BALSOL:

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

Tell your doctor if you are taking:

- Medicines used for high blood sugar (e.g. chlorpropamide).
- Medicines used to treat epilepsy (e.g. carbamazepine, oxcarbazepine).
- Medicines used to treat high levels of fat (cholesterol) in the blood (e.g. clofibrate).
- Cancer medicines (e.g. vincristine, ifosfamide and cyclophosphamide).
- Medicines used to treat depression (also known as selective serotonin reuptake inhibitors (SSRIs)) and mental health problems.
- Medicines used to treat hyperactivity, also known as ADHD (e.g. methamphetamine).
- Medicines used for pain and inflammation, also known as NSAIDs.
- Medicine used for bed-wetting, called desmopressin.
- Medicines used during labour (e.g. oxytocin).
- Medicine used to manage anti-diuretic hormone deficiency and diabetes insipidus, known as vasopressin.
- Terlipressin (medicine used to treat bleeding oesophageal varices, which is a condition where veins in your food pipe are enlarged because they have an increased blood flow.
- Corticosteroids or corticotropin (medicines used to reduce swelling or to treat hormone problems).
- Medicines used to treat infections (tetracyclines) such as doxycycline.
- Quinidine, flecainide (medicines used to treat heart problems).
- Amphetamines (medicines used to treat certain mental disorders and drowsiness).
- Ephedrine and pseudoephedrine (medicines used to treat colds and asthma).

- Potassium supplements.
- Medicines used to treat water retention and problems with passing urine such as potassium-sparing diuretics (e.g. amiloride, spironolactone, triamterene), ethacrynic acid, bumetanide, thiazides or furosemide.
- Angiotensin-converting enzyme inhibitors (ACE inhibitors) and angiotensin II receptor antagonists (medicines that are mainly used for controlling blood pressure and treating heart failure).
- Tacrolimus and ciclosporin (medicine used to prevent organ rejection).
- Muscle relaxants (e.g. suxamethonium).
- Medicines used to treat high blood pressure (e.g. mecamylamine).
- Medicines used to treat Alzheimer's disease (e.g. memantine).
- Medicines used to treat diabetes mellitus (e.g. chlorpropamide).
- Medicines used to treat mood disorders (e.g. lithium).
- Salicylates used to ease pains and reduce fever (e.g. aspirin).

BALSOL with food and drink:

There are no known interactions between BALSOL, food and drink.

Pregnancy and breastfeeding:

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

Driving and using machines:

BALSOL has no known effects on driving.

3. How BALSOL will be administered to you

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

You will not be expected to give yourself BALSOL. It will be given to you by a person who is qualified to do so.

BALSOL will be administered to you by intravenous infusion (infusion into a vein).

Your doctor will decide how much BALSOL will be given to you, at what rate it will be infused into your vein and for how long your treatment will last. This will depend on the severity of your condition, your age and weight.

Your health care provider will check that the BALSOL solution is tightly sealed, clear and without particles and is not past the expiry date stated on the label before giving you the infusion.

If you have the impression that the effect of BALSOL is too strong or too weak, tell your doctor of pharmacist.

If you receive more BALSOL than you should:

Since a health care provider will administer BALSOL, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of BALSOL:

Since a health care provider will administer BALSOL, it is unlikely that the dose will be missed.

4. Possible side effects

BALSOL can have side effects.

Not all side effects reported for BALSOL are included in this leaflet. Should your general health worsen or if you experience any untoward

effects while receiving BALSOL, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving BALSOL and tell your doctor immediately or go to the casualty department at your nearest hospital:

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

- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BALSOL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Hyperhydration (too much fluid in your body).
- Heart failure in patients with heart disorder or pulmonary oedema (fluid accumulation in the lungs).
- Low levels of potassium causing twitching, muscle weakness, “pins and needles” in the hands or feet, irritability or abnormal heart rhythm.
- Low levels of blood sugar and high concentration of sodium in the blood causing you to feel hungry, thirsty, nervous, confused,
  extreme irritation, and experience increased urination, shakiness or sweating.
- Too much acid in the blood, which many cause an increased rate of breathing (intracellular acidosis).
- Low levels of calcium causing involuntary contraction of your muscles.
- Low levels of sodium in the blood (hyponatraemia) that may affect the functioning or structure of your brain (encephalopathy). Symptoms may include headache, nausea, vomiting, seizures (fits) and coma.
- Newborn babies may have bleeding inside the skull.

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

Tell your doctor if you notice any of the following:

- Fluid accumulation in tissues causing swelling (oedema).
- 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).

- If BALSOL is administered incorrectly, it could cause the skin to die around the injection site.
- Receiving large volumes of this solution may lead to dilution of components of the blood and a decrease in the haematocrit (proportion of blood volume that is occupied by red blood cells).

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 or pharmacist. You can also report side effects to SAHPRA 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 BALSOL.

5. How to store BALSOL

Store at or below 25 °C.

Once opened BALSOL should be used immediately.

KEEP ALL MEDICINES OUT OF THE REACH OF CHILDREN.

- Do not use after the expiry date printed on the container.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BALSOL contains:

The active ingredients are sodium chloride, potassium chloride, magnesium chloride hexahydrate and sodium bicarbonate.

Each 1 000 ml contains:

Sodium chloride	6,0 g
Potassium chloride	0,3 g
Magnesium chloride hexahydrate	0,3 g
Sodium bicarbonate	2,3 g

The other ingredient is water for injection.

What BALSOL looks like and contents of the pack:

A clear, colourless, sterile solution.

1 000 ml polyethylene bottles.

1 000 ml PVC or **free***flex*® bags.

Not all container types may be marketed.

Holder of certificate of registration and manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten

Port Elizabeth 6020

South Africa

Tel.: 041 403 1600

This leaflet was last revised:

17 January 2021

Registration number:

H/24/176

Date of registration:

25 May 1976