APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

NEOLYTE® solution for infusion

Each 200 ml contains:

Potassium chloride	224 mg
Calcium chloride dihydrate	73,4 mg or
Calcium chloride hexahydrate	109,4 mg
Magnesium chloride hexahydrate	20,4 mg
Sodium lactate	448 mg
as sodium lactate solution 60 %	
Phosphoric acid 85 %	86,36 mg
Dextrose anhydrous	20,0 g or
Dextrose monohydrate	22,0 g

Content of electrolytes per 1 000 ml:

sodium ion (Na^+)	20 mmol/l
potassium ion (K^+)	15 mmol/l
chloride ion (Cl^-)	21 mmol/l
lactate	20 mmol/l
calcium ion (Ca^{2+})	2,5 mmol/l
magnesium ion (Mg^{2+})	0,5 mmol/l
phosphate	3,75 mmol/l.

Contains sugar (dextrose).

Osmolarity:	638 mOsm/l
pH (approximately):	4,0
Energy:	1 672 kilojoules.

Read the entire leaflet carefully before your child is given NEOLYTE

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

What is in this leaflet

1. What NEOLYTE is and what it is used for
2. What you need to know before your baby is given NEOLYTE
3. How NEOLYTE should be given
4. Possible side effects
5. How to store NEOLYTE
6. Contents of the pack and other information.

1. What NEOLYTE is and what it is used for

NEOLYTE is a solution that contains dextrose (a sugar also known as glucose), lactate and electrolytes. It is used to help restore the nutritional status of your child's body with adequate fluid, energy and salts. Your child may receive it for a number of reasons, such as malnutrition, too low potassium concentration, vomiting and diarrhoea.

2. What you need to know before your child is given NEOLYTE

Your child should not be administered NEOLYTE if he/she:

- is hypersensitive (allergic) to any of the active ingredients (listed in section 2) or other

ingredients of NEOLYTE (listed in section 6)

- has had an allergic reaction to maize (corn) products as dextrose may be manufactured from maize products
- has very weak kidneys and produces no or little urine
- has heart failure, a condition where the heart muscle does not pump blood as well as it should
- has high quantities of salts like sodium and chlorides in his/her blood (you will know this after a blood test)
- is only 28 days of age (or younger) and has to receive an antibiotic known as ceftriaxone.

If you think or know that any of these conditions applies to your child, inform the doctor or professional healthcare provider.

Warnings and precautions

Tell your child's doctor or healthcare provider before being given NEOLYTE, if you have previously been told that your child has:

- kidney failure, other kidney problems or kidney stones
- high levels of potassium in the blood (hyperkalaemia)
- tissue injury or burns
- swelling (oedema) and salt (sodium) retention
- shock and head injury
- liver problems
- low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatraemia)
- carbohydrate intolerance, high blood sugar or diabetes
- inadequate acid in your stomach or your blood is too alkaline
- already received a lot of liquids
- heart problems
- high levels of calcium in the blood (hypercalcaemia)

- or your child receives other medicines, particularly ceftriaxone (an antibiotic).

Too much NEOLYTE may cause congestion (swelling) of the lungs and limbs. Your doctor will examine your child and do regular blood tests to decide how much and for how long your child has to receive the treatment.

Other medicines and NEOLYTE

Always tell your healthcare provider if your child is taking any other medicine. (This includes complementary or traditional medicines.)

This is especially important with the following medicines, as they may interact with NEOLYTE. NEOLYTE may also interfere with the absorption and excretion of other medicines:

- An antibiotic used for bacterial infections known as ceftriaxone.
- Blood products.
- Medicines used for high blood pressure (such as angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists) and terlipressin (medicine used to treat oesophageal varices).
- Medicines used to suppress the immune system (such as tacrolimus and ciclosporin).
- Medicines used for inflammation (such as corticosteroids or carbenoxolone).
- A hormone called corticotropin that also occurs naturally in the body, which may be used as part of a medical test to check the functioning of your adrenal glands (glands found on top of the kidneys).
- Medicines used for swelling, known as potassium-sparing diuretics (such as amiloride, spironolactone, triamterene, alone or in combination) or potassium supplements.
- Vitamin D supplements.
- Medicines used for high blood sugar (such as chlorpropamide).
- Medicines used to treat epilepsy (such as carbamazepine or oxcarbazepine).
- Medicines used to treat high levels of fat (cholesterol) in the blood (such as clofibrate).
- Cancer medicines (such as vincristine, ifosfamide and cyclophosphamide).

- Medicines used to treat depression (also known as selective serotonin reuptake inhibitors (SSRIs)), mental health problems and mood disorders (e.g. lithium).
- Medicines used to treat hyperactivity, also known as ADHD (such as methamphetamine).
- Medicines used for pain, fever and inflammation (NSAIDs) such as aspirin.
- Medicine used for bed-wetting, called desmopressin.
- Medicine used to manage anti-diuretic hormone deficiency and diabetes insipidus, known as vasopressin.
- Heart medicines (such as digoxin).
- Cold and flu medicines containing pseudoephedrine.

These medicines may be affected by NEOLYTE or may affect how well it works. Your child may need different amounts of his/her regular medicines or may need to be given different medicines.

Pregnancy and breastfeeding

Not applicable, as NEOLYTE is intended for babies only.

Driving and using machines

Not applicable, as NEOLYTE is intended for babies only.

NEOLYTE contains dextrose

NEOLYTE contains 20 g dextrose anhydrous or 22 g dextrose monohydrate per 200 ml solution. Tell your child's doctor if he/she has diabetes or an intolerance for sugars. Dextrose is a type of sugar, manufactured from maize. Tell your child's doctor if he/she is allergic to maize products.

3. How you will be given NEOLYTE

You will not be expected to give NEOLYTE intravenous infusion to your baby. It will be given by a doctor or professional healthcare provider.

Your baby's doctor will choose the dose that is right for your child. The dosage depends on your child's size and his/her nutritional status, water and salt balance.

Your child's doctor will tell you how long his/her treatment with NEOLYTE will last as it will depend on his/her condition.

If you have the impression that the effect of NEOLYTE is too strong or too weak, tell your child's doctor of pharmacist.

If your child receives more NEOLYTE than he/she should

Since a healthcare provider will administer NEOLYTE, he/she will control the dosage. However, in the event of overdosage your child's doctor will manage the overdosage.

If your child missed a dose of NEOLYTE

Since a healthcare provider will administer NEOLYTE, it is unlikely that a dose will be missed.

4. Possible side effects

NEOLYTE can have side effects.

Not all side effects reported for NEOLYTE are included in this leaflet. Should your child's general health worsen, or he/she experiences any untoward effects while receiving NEOLYTE, please consult your child's doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop administration of NEOLYTE immediately:

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

These are all very serious side effects. If your child has them, he/she may have had a serious reaction to NEOLYTE and may need urgent medical attention.

Tell your child's doctor immediately if you notice any of the following after your child has received NEOLYTE:

- Changes in the way your child's heart beats such as an irregular heart rhythm.

This is a serious side effect. Your child may need urgent medical attention.

Tell your child's doctor or professional healthcare provider as soon as possible if you notice any of the following side effects (frequency unknown):

- Generalised swelling due to a build-up of fluid under the skin.
- Feeling anxious.
- Headache.
- Low blood pressure.
- Feeling tired, weak and irritable with swelling and muscle jerking that may progress to fits. This may be due to too much sodium salt in his/her blood (hypernatraemia).
- Nausea (feeling sick), lack of taste or loss of sensation in the mouth.
- Tingling and pricking sensation ("pins and needles").
- Reactions at the site of the infusion, including reddening of the skin, pain, inflamed skin, bruising or localised swelling. This may be due to leakage of the NEOLYTE infusion into the surrounding tissue.

These are all very serious side effects. If your child has them, he/she may have had a serious reaction to NEOLYTE. He/she may need urgent medical attention.

Your doctor will monitor your child for the following, as you may not notice these side effects yourself:

- Too much glucose, potassium or salt in the blood and electrolyte disturbances from unsuitable intravenous use of NEOLYTE, or if your kidneys do not function well.

If you notice any side effects not mentioned in this leaflet, please inform your child's doctor or

pharmacist.

Reporting of side effects

If your child gets side effects, talk to the doctor, pharmacist or nurse. 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 NEOLYTE.

5. How to store NEOLYTE

- Store at or below 25 °C.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Your child's healthcare professional will check that NEOLYTE is not past its expiry date as stated on the label and carton, before giving the infusion.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NEOLYTE contains

The active substances are (per 200 ml bag):

Potassium chloride	224 mg
Calcium chloride dihydrate	73,4 mg or
Calcium chloride hexahydrate	109,4 mg
Magnesium chloride hexahydrate	20,4 mg
Sodium lactate	448 mg
as sodium lactate solution 60 %	
Phosphoric acid 85 %	86,36 mg
Dextrose anhydrous	20,0 g or
Dextrose monohydrate	22,0 g

The other ingredient is water for injection.

What NEOLYTE looks like and contents of the pack

A clear, colourless to light straw-coloured solution.

200 ml flexible PVC or **free***flex* bags.

Holder of Certificate of Registration and Manufacturer

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