Amendment date: 28 May 2021
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APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

Lipovenoes 10 % PLR parenteral infusion

Each 100 ml contains:

Soybean oil 10,0 g

Egg lecithin 0,6 g

Glycerol 2,5 g

Contains sugar (as glycerol 2,5 g)

Read all of this leaflet carefully before you start using this medicine because it may contain important information for you.

- *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 provide.*
- *Lipovenoes 10 % PLR 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 Lipovenoes 10 % PLR is and what it is used for

2. What you need to know before you use Lipovenoes 10 % PLR

3. How to use Lipovenoes 10 % PLR

4. Possible side effects

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6. Contents of the pack and other information

1. What Lipovenoes 10 % PLR is and what it is used for

Lipovenoes 10 % PLR is a fat emulsion for parenteral nutrition, i.e. that is given to you via a vein (IV drip).

Lipovenoes 10 % PLR is a source of energy and essential fatty acids as part of total parenteral nutrition regimens either alone or in conjunction with amino acids and carbohydrate solutions.

2. What you need to know before you use Lipovenoes 10 % PLR.

Do not use Lipovenoes 10 % PLR

- if you are hypersensitive (allergic) to egg-, soya- or peanut protein or any of the other ingredients of Lipovenoes 10 % PLR (listed in section 6).
- If you have liver damage
- If you have a fat metabolism disorder (Metabolic disturbances such as lipoprotein lipase deficiency)
- If you have impaired lipid metabolism, including lipoid nephrosis and hyperlipidaemia
- If you have severe blood clotting
- If you have a tendency to bruise or bleed easily
- If you have uncontrolled diabetes mellitus
- If you are pregnant and in the first trimester
- If you have all acute and life-threatening diseases such as collapse and shock, recent incidences of inadequate blood supply to the heart (cardiac infarction), stroke, blockage in the artery (embolism) and undefined coma status
- If you have untreated disorders of the salt and fluid balance in the form of salt and water

deficiency, reduced potassium levels in the blood serum and/or excessive fluid. (General contra-indications for parenteral nutrition include hypokalaemia, hyperhydration and hypotonic dehydration.

Warnings and precautions

Tell your doctor or healthcare provider if Lipovenous 10 % PLR may be contraindicated in you before being given the medicine.

Special care should be taken with Lipovenoes 10 % PLR:

Serum triglycerides must be monitored daily and blood sugar, acidbase balance, electrolyte status, fluid input and output, and blood count at appropriate intervals. Serum triglyceride levels should not exceed 3 mmol/l during an on-going fat infusion.

There are indications that peroxide formation in the infusion solution cannot be completely ruled out during phototherapy if fat emulsions are administered at the same time due to the effect of light.

Children and adolescents

Therefore, as a precaution it is recommended that the fat emulsion should be protected from the effect of light in newborn infants receiving phototherapy.

Paediatric patients with increased bilirubin levels need to be monitored when receiving Lipovenoes 10 % PLR.

Other medicines and Lipovenoes 10 % PLR

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

Pregnancy, breastfeeding and fertility

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 taking this medicine.

Driving and using machines

It is not always possible to predict to what extent Lipovenoes 10 % PLR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Lipovenoes 10 % PLR affects them.

Lipovenoes 10 % PLR contains:

Sodium oleate, sodium hydroxide, water for injection.

3. How to use Lipovenoes 10 % PLR

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

Always use Lipovenoes 10 % PLR exactly as your doctor has told you. Check with your doctor if you are not sure.

The usual dose is:

For neonates, infants and children:

If not otherwise prescribed, 1 to 2 g fat/kg weight/day = 10 to 20 ml Lipovenoes 10 % PLR/kg body weight/day.

With increased energy requirements:

Up to 3 g fat/kg weight/day = 30 ml Lipovenoes 10 % PLR/kg body weight/day.

The dosage and dosage increments are governed by the infant’s ability to eliminate fat which should be checked daily.

For adults:

If not otherwise prescribed, 1 to 2 g fat/kg weight/day = 10 to 20 ml Lipovenoes 10 % PLR/kg body weight/day.

Infusion rate:

A maximum of 0,125 g fat/kg body weight /hour = 1,25 ml/kg body weight/hour is infused.
However, at the beginning of parenteral nutrition with fat, a slow dosage with a maximum of 0,05 g fat/kg body weight/hour is recommended.
At a body weight of 70 kg, infusion is begun with 10 drops/minute and increased gradually after 30 minutes to a maximum of 26 drops per minute.

Fat elimination test:

In cases where daily infusions of intravenous fat for more than one week are indicated, the ability of the patients to eliminate administered fat should be tested.
Before starting the infusion, a fasting blood sample is taken for ESR (citrate). The sample is centrifuged at 1 200 to 1 500 rpm. If the plasma is milky or markedly opalescent, the planned infusion should be postponed.

Your doctor will tell you how long your treatment with Lipovenoes 10 % PLR will last.
If you have the impression that the effect of Lipovenoes 10 % PLR is too strong or too weak, tell your doctor or pharmacist.

If you receive more Lipovenoes 10 % PLR than you should:

Since a health care provider will administer Lipovenoes 10 % PLR, he-/-she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use Lipovenoes 10 % PLR:

Since a health care provider will administer Lipovenoes 10 %, it is unlikely that the dose will be missed.

4. Possible side effects

Lipovenoes 10 % PLR can have side effects.

Not all side effects reported for Lipovenoes 10 % PLR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Lipovenoes 10 % PLR, please consult your health care provider for advice.

If any of the following happens, stop using Lipovenoes 10 % PLR and tell your doctor immediately.

The following possible early reactions with the administration of fat emulsions have been reported and the frequencies are unknown:

Vascular disorders:

Persistent and painful erection of the penis (priapism) (very rare cases)

Respiratory, thoracic and mediastinal disorders:

Shortness of breath

Gastrointestinal disorders:

Nausea, vomiting, lack of appetite

Skin and subcutaneous tissue disorders:

Abnormal colouring of a person’s skin (Pigmentation) of tissues may occur after prolonged therapy with fat emulsions

Musculoskeletal, connective tissue and bone disorders:

Pains in the head, back, bones, chest and loins

General disorders and administration site conditions:

Slight rise in temperature (fever and chills)

Heat/cold sensation

Abnormal feeling of warmth (flushes) or blueness (cyanosis)

Investigations:

The prolonged infusion of soybean oil emulsion or its administration to patients with impaired liver metabolism has been associated with the “overload syndrome”, which exhibits the following symptoms, with frequencies unknown.

Blood and lymphatic system disorders:

Bone marrow depression

Iron deficiency of the blood (anaemia)

Reduction in blood platelets (thrombocytopenia)

Reduction in white blood cells (leucopenia)

Spontaneous bleeding

A change or reduction of some coagulation factors, (e.g. bleeding time, coagulation time, prothrombin time, thrombocyte count)

Hepatobiliary disorders:

Abnormal enlargement of the liver and spleen (hepatosplenomegaly)

Enlargement of the liver (hepatomegaly) with or without jaundice (icterus)

Pathological liver function tests.

Investigations:

Increased blood fat levels (hyperlipidaemia)

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 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 Lipovenoes 10 % PLR.

5. How to store Lipovenoes 10 % PLR

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. Protect from light.

When used in neonates and children below 2 years, protect from light exposure, until administration is completed.

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 Lipovenoes contains:

Each 100 ml contains:

Soybean oil 10,0 g

Egg lecithin 0,6 g

Glycerol 2,5 g

Inactive ingredients:

Sodium oleate, sodium hydroxide, water for injection.

What Lipovenoes 10 % PLR looks like and contents of the pack

White, homogeneous emulsion

Infusion bottles containing 100 ml, 250 ml, and 500 ml.

(Hospital packs ~~available~~ containing 10 infusion bottles are available).

The container closure system consists of a glass bottle which is closed with an elastomeric stopper.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Limited

Stand 7, Growthpoint Park

162 Tonneti Street

Halfway House, Extension 7

1682

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