APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SMOFKABIVEN - Emulsion for infusion

Amino acid solution with electrolytes

Glucose 42 %

Lipid emulsion

Contains sugar as Glucose (127 g per 1 000 ml)

Read all of this leaflet carefully before you are given SMOFKABIVEN

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

1. What SMOFKABIVEN is and what it is used for

SMOFKABIVEN consists of a three-chamber bag system including:

1. Amino acid solution with electrolytes
2. Glucose 42 %
3. Lipid emulsion

SMOFKABIVEN provides essential nutrients to adults and children aged 2 years and above through the intravenous route, when other routes of administration are not possible, inadequate, or contraindicated.

2. What you need to know before you are given SMOFKABIVEN

SMOFKABIVEN should not be administered to you:

- if you are hypersensitive (allergic) to sodium chloride, potassium chloride, magnesium chloride hexahydrate, sodium bicarbonate or any of the other ingredients of SMOFKABIVEN (listed in section 6)
- if you have too much fat in the blood (hyperlipidaemia)
- if you have serious liver disease
- if you have blood clotting problems (coagulation disorders)
- if your body has problems using amino acids
- if you have serious kidney disease without access to dialysis
- if you are in acute shock
- if you have too much sugar in your blood (hyperglycaemia)
- if you have high blood (serum) levels of the salts (electrolytes)
- if you have fluid in the lungs (acute pulmonary oedema)
- if you have too much body fluid (hyperhydrated)
- if you have heart failure that is not treated
- if you have a defect in your blood clotting system (haemophagocytotic syndrome)

- if you are in an unstable condition, such as after serious trauma, uncontrolled diabetes, stroke, blood clot, metabolic acidosis (a disturbance resulting in too much acid in the blood), serious infection (severe sepsis), coma and if you don't have enough body fluid (hypotonic dehydration).
- In children under 2 years of age.

Warnings and precautions

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

- if you have pancreatitis (inflammation of the pancreas);
- if you have a liver disorder;
- if you have a kidney disorder;
- if you have an underactive thyroid gland;
- if you have blood poisoning (sepsis);
- if you have diabetes mellitus;
- if you have electrolyte disturbances.

If your blood needs to be tested, tell the health care provider taking the sample that you are receiving SMOFKABIVEN. SMOFKABIVEN may interfere with some laboratory tests.

Tell your doctor or health care provider if you feel weak, feverish or nauseous. You may be suffering from fat overload disease.

Other medicines and SMOFKABIVEN

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 take or use:

- Heparin (a blood thinner) that prevents the formation of blood clots;

- Insulin (helps to keep your blood sugar level from getting too high (hyperglycemia) or too low (hypoglycemia));
- Soy-bean oil, as it contains vitamin K1. Your doctor should know you take this if you also take medicines like warfarin to thin your blood.

Pregnancy and breastfeeding

Safety has not been demonstrated in pregnancy and lactation

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 SMOFKABIVEN

Driving and using machines

It is not always possible to predict to what extent SMOFKABIVEN 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 SMOFKABIVEN affects them.

SMOFKABIVEN contains Glucose

This should be taken into account in patients with diabetes mellitus

Some of the active ingredients in SMOFKABIVEN are soy-bean oil, fish oil and egg phospholipids, which may cause allergic reactions (see POSSIBLE SIDE EFFECTS). You may be allergic to soy-bean if you are allergic to peanuts. Tell the health care provider immediately if you have any sign of an allergic (such as fever, shivering, rash, swelling or problems breathing). See POSSIBLE SIDE EFFECTS for more information.

3. How SMOFKABIVEN will be administered to you

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

Your doctor will administer SMOFKABIVEN to you in the hospital with an injection directly

into a vein.

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

If you are given more SMOFKABIVEN than you should

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

If you forget to take SMOFKABIVEN

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

4. Possible side effects

SMOFKABIVEN can have side effects.

Not all side effects reported for SMOFKABIVEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving SMOFKABIVEN, please consult your health care provider for advice**.**

If any of the following happens, tell your doctor immediately:

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

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

Tell your doctor if you notice any of the following:

Side effects that occur frequently include:

- Increase in your body temperature

Side effects that occur less frequently include:

- Lack of appetite, nausea, vomiting
- Chills, pale skin, dizziness, headache
- High blood pressure or low blood pressure
- Skin reactions where you have been injected (rashes, hives)
- Pain of the neck, back, bones, chest or loins
- Difficulty breathing (dyspnoea)
- Rapid heart beat
- Sensations of hot and cold
- Bluish or greyish colour of the skin, nails, lips or around the eyes (cyanosis)

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 SMOFKABIVEN.

5. How to store SMOFKABIVEN

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Do not freeze.

Store in over pouch.

For single use only. Any mixture remaining after infusion must be discarded.

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

6. Contents of the pack and other information

What SMOFKABIVEN contains

Active substance	**Per 1 000 ml**
Alanine	7,1 g
Arginine	6,1 g
Glycine	5,6 g
Histidine	1,5 g
Isoleucine	2,5 g
Leucine	3,8 g
Lysine (as acetate)	3,4 g
Methionine	2,2 g
Phenylalanine	2,6 g
Proline	5,7 g
Serine	3,3 g
Taurine	0,5 g
Threonine	2,2 g
Tryptophan	1,0 g
Tyrosine	0,20 g
Valine	3,1 g
Calcium chloride (as dihydrate)	0,28 g
Sodium glycerophosphate (as hydrate)	2,1 g
Magnesium sulphate (as heptahydrate)	0,61 g
Potassium chloride	2,3 g
Sodium acetate (as trihydrate)	1,7 g
Zinc sulphate (as heptahydrate)	0,0066 g
Glucose (as monohydrate)	127 g
Soya-bean oil, refined	11,4 g
Medium-chain triglycerides	11,4 g
Olive oil, refined	9,5 g
Fish oil, rich in omega-3-acids	5,7 g

The other ingredients are:

Amino acid solution with electrolytes (Aminoven 10 %)

• Acetic acid glacial

• Water for injection

Glucose 42 %

• Hydrochloric acid

• Water for injection

Lipid emulsion (SMOFlipid 20 %)

• all-rac-α-Tocopherol

• Purified egg phospholipids

• Glycerol, anhydrous

• Sodium oleate

• Sodium hydroxide

• Water for injections

What SMOFKABIVEN looks like and contents of the pack

SMOFKABIVEN is packed into a three-chamber inner bag made of or Biofine, a high barrier overpouch made from Oxnil™ or HVL 9003 film and an oxygen absorber, Ageless® FX-PAJ. The inner bag is filled with amino acid solution corresponding to Aminoven 10 %, Glucose 42 % and SMOFlipid 20 % in separate chambers divided by peelable seals.

Pack sizes:

Biofine bags

1 x 493 ml, 4 x 493 ml

1 X 986 ml, 4 X 986 ml

1 X 1477 ml, 4 X 1477 ml

1 X 1970 ml, 4 X 1970 ml

1 X 2463 ml, 3 X 2463

Three-chamber bag consisting of amino acid solution 10 %, glucose solution 42 % and lipid emulsion corresponding to SMOFlipid 20 %.

Amino acid solution with electrolytes (Aminoven 10 %):

A clear solution, colourless to slightly yellow and practically free from particles, in a three-chamber bag.

Glucose 42 %:

Clear; not more intensely coloured than Y6/BY6

Smoflipid 20 %:

A white emulsion.

Mixed three-chamber bag:

A white emulsion in an open/mixed three-chamber bag.

Holder of Certificate of Registration

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