PATIENT INFORMATION LEAFLET

1. SCHEDULING STATUS

S3

2. PROPRIETARY NAME, STRENGTH AND DOSAGE FORM

Kabiven Peripheral Emulsion for infusion

Read all of this leaflet carefully before you receive Kabiven Peripheral.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

Kabiven Peripheral 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.

3. WHAT KABIVEN PERIPHERAL CONTAINS

Kabiven Peripheral consists of a three chamber bag. The individual chambers contain a glucose solution, an amino acid solution and a fat emulsion. Contains sugar (as glucose 100 g, glycerol 4,4 g)

4. WHAT KABIVEN PERIPHERAL IS USED FOR

Kabiven Peripheral is used in parenteral nutritional. Parenteral nutrition is a way of supplying the nutritional needs of the body by bypassing the digestive tract and giving the nutrients directly into a vein. It is given when a patient is unable to eat or where tube-feeding is not possible.

5. BEFORE YOU ARE GIVEN KABIVEN PERIPHERAL

You should not receive Kabiven Peripheral:

- if you are hypersensitive to egg-, soy- or peanut protein or to any of the other substances in this product
- if you have high levels of fats in your blood
- if you have liver or kidney problems
- if you have severe blood clotting disorders
- if your body is unable to metabolise amino acids effectively
- if you have acute shock
- if you have high levels of sugar in your blood

Kabiven Peripheral should not be given to infants and children under 2 years of age.

Special care should be taken with Kabiven Peripheral:

- Your body's ability to remove fats should be monitored.
- Your blood level of salts and fluid should be corrected before an infusion is started.
- Frequent monitoring of your blood sugar, salts, fluid balance and liver enzymes should be performed.
- You will be carefully monitored by the healthcare professionals at the beginning of the infusion. If any abnormal signs occur, the infusion must be stopped immediately.
- If you develop any signs of an allergic reaction, the infusion should be stopped immediately.
- If you have impaired fat metabolism. This many be caused by decreased kidney function, diabetes, inflammation of your pancreas, impaired liver function, an underactive thyroid gland, or bacterial infection of your bloodstream or body tissues.
- If you have a tendency to retain salts.

Heparin may cause a release of enzymes into the blood. This may result in an increased breakdown of fats in the blood followed by a decease in fat clearance.

Soybean oil has a natural content of vitamin K_1. This may interfere with coumarin type medicines (medicines used in blood clotting disorders) and the doctor must monitor your blood levels.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving Kabiven Peripheral.

If you are pregnant or breastfeeding your baby, you should not receive Kabiven Peripheral.

Using other medicines with Kabiven Peripheral

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

6. HOW KABIVEN PERIPHERAL WILL BE GIVEN

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

The dose will be adjusted depending on your condition, body weight and nutritional requirements. Kabiven Peripheral is given by intravenous infusion into a peripheral vein (slow injection of fluid into a vein in the hands, arms, feet or legs). One bag of the emulsion will be given to you over a 12-24 hour period.

Any portion of the medicine remaining after infusion should be discarded.

If you receive more Kabiven Peripheral than you should

Since a healthcare professional will administer Kabiven Peripheral, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

7. POSSIBLE SIDE EFFECTS

Kabiven Peripheral can have side effects, such as:

- Fever or shivering and chills
- Hypersensitivity reactions with a skin rash and itching
- High or low blood pressure
- Headache
- Tiredness
- Thrombophlebitis (inflammation of the vein related to a blood clot)
- Nausea, vomiting and abdominal pain
- Increase in the number of liver enzymes
- Respiratory symptoms like tachypnoea (breathing faster or more deeply than necessary)
- Breakdown of blood cells

If your body cannot remove fats you may develop *fat overload syndrome*. This is characterised by high levels of fats in your blood, fever, liver toxicity, spleen toxicity, blood disorders and coma.

Not all side effects reported for Kabiven Peripheral are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Kabiven Peripheral, please consult your doctor, pharmacist or other healthcare professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

8. STORING AND DISPOSING OF KABIVEN PERIPHERAL

Store all medicines out of reach of children.

The unmixed product must be stored at or below 25 ºC in the overpouch. It must not be frozen. The mixed product can be stored at or below 25 ºC for 48 hours or at 2 – 8 º C for 6 days.

9. PRESENTATION OF KABIVEN PERIPHERAL

Clear, colourless bags in three sizes: 1 440 ml, 1 920 ml and 2 400 ml

10. IDENTIFICATION OF KABIVEN PERIPHEAL

The bag consists of a multi-chamber inner bag with an overpouch. The three chambers of the inner bag are separated by peelable seals. These layers consist of:

- Glucose 11 %: A clear almost colourless solution
- Vamin 18 Novum: A clear solution, colourless to slight yellow
- Intralipid 20 %: A white homogenous emulsion

After mixing a white homogenous emulsion is formed.

11. REGISTRATION NUMBER

38/25.2/0165

12. NAME AND BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION

Fresenius Kabi South Africa (Pty) Ltd
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13. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

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