Kabiven® G11% and G19%

G11% contains 2.4% amino acids, 3.5% triglycerides, 6.8% glucose and 0.7% electrolytes. G19% contains 3.3% amino acids, 3.9% triglycerides, 9.7% glucose and 0.7% electrolytes

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Kabiven. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you being given Kabiven against any benefits they expect it will have for you.

Please read this leaflet carefully. If you have any questions or are unsure about anything, please ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What is Kabiven used for and how does it work

Kabiven is a sterile emulsion which provides your body with nutrition by the intravenous route. When the intake of nutrients or food into the mouth or directly into the gut is not possible, or it is not enough to supply the body's needs, then intravenous nutrients or foods can be given. This is especially important for people whose bodies are under physical stress from illness or recent surgery. During illness or after surgery the body requires nutrition or food.

Kabiven G19% contains 3.3% amino acids, 3.9% triglycerides (soya oil), 9.7% glucose and 0.7% electrolytes.

Kabiven G11% contains 2.4% amino acids, 3.5% triglycerides, 6.8% glucose and 0.7% electrolytes.

Kabiven is usually given together with trace elements and vitamins to provide a complete intravenous diet.

Before you are given Kabiven

You should NOT be given Kabiven if

- You have had an allergic reaction to egg-yolk containing foods, peanut or soy products.
- You have an allergy to any of the ingredients contained in Kabiven as listed at the end of this leaflet.
- You have an inability to break down fats
- You have an inability to break down amino acids, for example an inherited condition known as phenylketonuria.
- You have severe liver failure.
- You have severe kidney failure (when dialysis facilities are not available).
- You are suffering from a very serious problem with your blood circulation.
- You have too much fluid in your body.
- You have too much acid in your blood, also called metabolic acidosis.
- You have a build up of fluid in your lungs and
- You have certain untreated heart problems.

- You are suffering from a blood disease or an infection of the blood.
- You are experiencing a sudden decrease in blood pressure.
- You have too much sugar in your blood.
- You have too much electrolytes in your blood.
- There is not enough water content in your body.
- You are suffering from a severe unstable medical condition.

If you are not sure whether any of these apply to you, check with your doctor.

You should tell your doctor BEFORE given Kabiven if the answer to any of the following questions is YES.

- Are you pregnant or trying to become pregnant?
- Are you breastfeeding?
- Are you allergic to proteins of eggs, peanuts or soy or any other medicines or any other substances, such as foods, preservatives or dyes?
- Do you have liver or kidney disease?
- Are you a diabetic?
- Do you have a disease of the pancreas?
- Do you have a disorder of the thyroid gland?
- Do you have a blood infection?
- Is there not enough oxygen being supplied to your cells?
- Do you have too much lactic acid in your body?
- Is your blood very concentrated?

- Are you taking anticoagulants (medicines for preventing blood clotting)?
- Are you taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop. These medicines may affect the action of Kabiven or may affect how well Kabiven works.

If you have not told your doctor about any of the above, tell your doctor before you are given Kabiven.

How is Kabiven given

Kabiven consists of a three chamber bag containing glucose, amino acids and electrolytes and soya oil. These solutions/emulsions are mixed by pulling apart the seals between the chambers and turning the bag upside down several times.

How much will be given:

The dose of Kabiven which you will require will be determined by your doctor or pharmacist. Your doctor will supervise your treatment with Kabiven.

How is it given:

Kabiven G19% and Kabiven G11% are usually given as a continuous infusion into a peripheral or central vein. An electronic pump may be used to control the speed of the infusion of drip.

If you are given too much (overdose)

This rarely happens as Kabiven is administered under the care of a trained professional in a hospital or clinic setting.

However, if you are given Kabiven too quickly or too much, you may experience the following side effects: feeling sick (nausea and vomiting) or become flushed and sweaty.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

Otherwise, immediately telephone your doctor or contact the Poisons Information Centre in your country.

Australia: 13 11 26 New Zealand: 0800 764 766.

Side Effects

Like all medicines, Kabiven can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- a rise in your body temperature
- shivering, chills
- nausea and vomiting
- tiredness
- headaches

Tell your doctor as soon as possible if you notice any of the following:

- abdominal pain
- persistent painful erection of the penis which occurs without sexual arousal

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

- serious allergic reactions (skin rash and hives);
- breathing difficulties (rapid breathing)
- effects on blood pressure

If any of these side effects occurs, or if you notice any side effects not listed in this leaflet, please contact your doctor or a pharmacist.

Storage

The expiry date of Kabiven is on the label of the pack. Kabiven

should not be used if the expiry date has passed.

Kabiven should be stored below 25°C, but not frozen. Do not use Kabiven if it has been frozen.

The contents of each bag of Kabiven are for single infusion only. Any unused Kabiven should be discarded. Do not use Kabiven if it is discoloured.

Product Description

What it looks like:

Kabiven is supplied in 2 types of plastic bag consisting of three chambers. One chamber (glucose 19% for Kabiven G19% or glucose 11% for Kabiven G11%) contain a clear, almost colourless solution, the second chamber (Vamin 18 Novum) contain a clear, colourless to slightly yellow solution while the third chamber (Intralipid 20%) contains a milky white emulsion.

Ingredients

Kabiven contains the active ingredients alanine, arginine, aspartic acid, calcium chloride dihydrate, glucose monohydrate, glutamic acid, glycine, histidine, isoleucine, leucine, lysine hydrochloride, magnesium sulfate heptahydrate, methionine, phenylalanine, potassium chloride, proline, serine, sodium acetate trihydrate, sodium glycerophosphate, soya oil, threonine, tryptophan, tyrosine and valine.

It also contains the inactive ingredients glycerol, egg lecithin, sodium hydroxide, glacial acetic acidand water for injections.

Kabiven does not contain any preservative.

Kabiven does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Kabiven G19% supplies the following calories:

- 1026 mL 900 kcal
- 1540 mL 1400 kcal
- 2053 mL 1900 kcal
- 2566 mL 2300 kcal

Osmolality: Approximately 1230 mOsm/kg water

pH: Approximately 5.6.

Kabiven G11% supplies the following calories:

- 1440 mL 1000 kcal
- 1920 mL 1400 kcal
- 2400mL 1700 kcal

Osmolality: Approximately 830 mOsm/kg water

pH: Approximately 5.6.

Kabiven comes in different bag sizes and can be identified by AUST R numbers:

Excel & Biofine Bags

Kabiven G19% 1026 mL: AUST R 97889 1540 mL: AUST R 97890 2053 mL: AUST R 97891 2566 mL: AUST R 97892

Kabiven G11% 1440 mL: AUST R 97893 1920 mL: AUST R 97894 2400 mL: AUST R 97895

Further Information

More detailed information is available from your doctor or pharmacist. Therefore, if you have any concerns about the information or about Kabiven ask your doctor or pharmacist.

Sponsor

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Date of information

This leaflet was prepared in 8th July 2016