

IVELIP®

Injection, Emulsion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **IVELIP®. 10% IVELIP 20% [IVELIP®]**. It does not contain all of the available information. All medicines have risks and benefit. Your doctor has weighed the risks of you using **IVELIP®** against the benefit he or she may expect it will have for you.

It does not take the place of talking to your doctor or pharmacist. If you have any concerns about being administered this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine, as you may need to read it again.

What IVELIP® is used for and how it works

IVELIP® is a sterile fat emulsion containing soya oil as an active component. It is used as a source of energy and for correction of an essential fatty acids deficiency, and is given as an infusion directly into your veins. **IVELIP®** is intended to provide you with nourishment (essential fatty acids) whilst you are unable to consume food by mouth.

Following an infusion of **IVELIP**, the fat and triglyceride component are released from the emulsion, and are subsequently broken down into fatty acid and glycerol in the liver. The free fatty acid is transported into muscle tissue, where it is converted into energy or transformed back into triglyceride and stored as a source of energy as fat in subcutaneous tissue

Before you are given IVELIP®

IVELIP IV infusion should not be given to you if:

- you have had an allergic reaction to egg-yolk containing foodstuffs or soybean products. Some of the symptoms of an allergic reaction may include skin rash, swelling of the face, lips or tongue, which may cause difficulty swallowing or shortness of breath.
- you are suffering from liver disease or too much fat or triglyceride in your blood circulation.

You must tell your doctor if:

- you have any other medical condition, especially pancreatitis (inflamed pancreas), liver disease, high cholesterol or blood clotting problems
- you are pregnant or breastfeeding
- you are taking prescription medication, such as heparin
- you are taking any non-prescription drug including nutritional supplements, purchased from your pharmacy, supermarket or health food stores.

Other precautions:

- **Use in the elderly:** no additional precautions for the elderly.
- **Paediatric (children) use:** The use of IVELIP® in very small and premature infants must be with caution. The doctor will regularly monitor your child's progress whilst on IVELIP®. Please ask your doctor about the benefits and risks in these cases.

How is IVELIP® to be given

How much will be given:

Your doctor will determine the amount of IVELIP® that is appropriate for you.

The medicine is a slow infusion and should be given by using special equipment and supervised by a health professional (doctor or trained nurse).

How will it be given?

IVELIP® is directly injected into your vein (intravenously). The needle is normally placed in a large vein. Your doctor knows which of your veins to use. Usually, you will need to stay in a health institution (hospital, nursing home, etc). IVELIP can be infused concurrently with other type of source of nutrients, amino acids and glucose, in order to minimise unwanted reactions.

If you miss a dose

This treatment needs to be given or taken on a regular basis. If a dose has been missed, administer the missed dose as soon as possible, unless it is almost time for the next dose.

In case of overdose

As the doctor or nurse giving you the IVELIP fat emulsion by slow infusion (drip) has had experience in the use of this sort of medication procedure, it is unlikely that you will be given an overdose. However, an impairment of your kidney function, may lead to an overdose syndrome, known as fat overload. In such case your health professional will reverse the condition by discontinuing the IVELIP infusion.

Side Effects

Most people do not have adverse reactions. However, as with most medicines, IVELIP® can sometimes cause unwanted side effects. These may include nausea, vomiting, skin rash, headache, dizziness, sweating, yellow skin or eyes, or changes in blood pressure. Tell your doctor or pharmacist as soon as possible if you have any of these symptoms or do not feel well while you are taking IVELIP®.

Tell your health professional on duty immediately if any of the following happen; swelling of the face, lips, mouth or difficulty in breathing. He/she will take appropriate action to promptly correct this serious allergic reaction, known as "anaphylactic shock".

Product Descriptions

What does IVELIP® looks like:

IVELIP® is presented in a glass bottle and is a milky white solution.

It is available in two strengths:

IVELIP® 10% in sizes of 100mL, 250mL and 500mL bottle,

IVELIP® 20% in sizes of 100mL, 250mL 500mL and 1 Litre bottle.

Ingredients:

Each bottle of IVELIP[®] contains;

Active ingredients: purified soya oil (IVELIP[®] 10%: 100g of soya oil/ litre; IVELIP[®] 20% - 200g of soya oil/ litre)

Inactive ingredients: Egg Lecithin, Glycerol, Sodium Oleate, and Ascorbyl palmitate.

Storage Conditions

This product should be stored at a temperature below 25°C. The product should be protected from freezing and from light exposure. Discoloured solution should not be used. Any remaining product from an opened bottle must be discarded. IVELIP[®] contains no preservative.

Where to go for further information?

You may ask your doctor or pharmacist on any aspect of your treatment.

Name and Address of Sponsor

Baxter Healthcare Pty Ltd.
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Old Toongabbie, NSW 2146
Australia

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