

ClinOleic

soya oil and olive oil emulsion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about **ClinOleic 20%**. It does not contain all of the available information. All medicines have risks and benefits. Your doctor has weighed the risks of you using ClinOleic against the benefit they 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.

What ClinOleic is used for

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

Before you are given ClinOleic

ClinOleic should not be given to you if:

- you have an allergy to any ingredient listed at the end of this leaflet;
- 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, peeling of the skin and swelling of the face, lips or tongue causing difficulty swallowing or shortness of breath;
- you have one of the following conditions:
 - an abnormal level of lipids in the blood
 - uncontrolled diabetes, lactic acidosis
 - a blood or other infection
 - severe liver disease
 - blood clotting problems
 - kidney disease
 - heart attack
- The expiry date printed on the pack has passed.

You must tell your doctor if you:

- are fluid overloaded or overhydrated;
- have diabetes;
- have liver disease
- are taking any prescription medicine
- are taking any other medicines including nutritional supplements, purchased from your pharmacy, supermarket or health food stores, , in particular warfarin;
- are pregnant;
- are breastfeeding.

The doctor will regularly monitor your condition whilst on ClinOleic. Please ask your doctor about the benefits and risks of using this medicine.

Other precautions:

Paediatric (children) use:

ClinOleic must be used with caution in very small and premature infants, especially in the case of jaundice. The doctor will regularly monitor your child's progress whilst on

ClinOleic. Please ask your doctor about the benefits and risks in these cases.

How ClinOleic is given

How much is given:

Your doctor will decide how much ClinOleic will be given to you, which depends on your need and condition.

How it is given:

ClinOleic will be given at a slow rate (drip) of injection by your health professional. Usually, you will need to stay in a health institution (hospital, nursing home, etc.) but in some cases at home, as it requires a special medical equipment to deliver the medicine into your circulation. A cannula (administration needle) is placed in a vein by your doctor or nurse.

The infusion is for single use and for one person only. Any unused portion must be discarded and not used later, either for you or anyone else.

ClinOleic may be given at the same time as other intravenous nutrition solutions such as glucose and amino acids.

Overdose

The doctor or nurse giving you the ClinOleic has had experience in the use of this sort of medicine, so it is unlikely that you will be given an overdose. However, in case of an overdose, the infusion will be discontinued and another treatment may be needed. You may experience some of the effects listed under "Side Effects" below.

While you are receiving ClinOleic

Discuss with your doctor your progress whilst receiving ClinOleic, especially if any complications occur during the first few days of therapy. Frequent clinical evaluation and laboratory tests may be required. As ClinOleic is normally given in a hospital, your nurse provider will take records of your progress and any unexpected reactions.

Side Effects

As with any medicines, some side effects may occur.

Undesirable side effect such as fever, itching, nausea, vomiting, diarrhoea, abdominal pain, back pain, muscle spasms, passing large amounts of urine, excessive thirst and having a dry mouth and skin, low blood pressure, hot flush, shortness of breath, yellowing of the skin and eyes, dark coloured urine, unusual weakness, rash, and generally feeling unwell.

Always tell your doctor or nurse if you have any unexpected effects during or after receiving ClinOleic and they worry you.

In rare circumstances, more serious side effects may occur such as chest pain, fast or slow heartbeat, or swelling of the face, lips or mouth causing breathing difficulties. If these occur, tell your health professional on duty immediately. These may be symptoms of a serious allergic reaction. Your health professional will take appropriate action promptly, such as stopping the infusion.

Product Description

What ClinOleic looks like

It is a milky white emulsion filled in plastic bag or glass bottle packaged in a protective over wrap.

It is available in different sizes:

ClinOleic in sizes of 100mL, 125mL, 250mL, 500mL and 1000mL glass bottle, ClinOleic in sizes of 100mL, 250mL, 350mL, 500mL and 1000mL plastic bag.

Ingredients

Active ingredients:

Mixture of refined olive oil (approximately 80%) and refined soya oil (approximately 20%), 200g of mixture/litre.

Other ingredients:

- egg lecithin;
- glycerol;
- sodium oleate;
- water for injections and
- ascorbyl palmitate.

Storage

ClinOleic will be stored in the pharmacy or the hospital ward. It is recommended that the product be stored in a cool dry place, protected from light, where the temperature stays below 25°C.

Where can you get more information?

You can get more information from your doctor or pharmacist.

Name and Address of Sponsor

Baxter Healthcare Pty Ltd.
1 Baxter Drive
Old Toongabbie, NSW 2146
Australia

Australian Registration number:

ClinOleic 20% bottle AUST R 97538
ClinOleic 20% bag AUST R 97537

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