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Baxter

PACKAGE LEAFLET: INFORMATION FOR THE USER

ClinOleic 20% Emulsion for infusion Refined olive oil and refined soya bean oil

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet, see section 4.

In this leaflet:

- 1 What ClinOleic is and what it is used for
- 2 What you need to know before you are given ClinOleic
- 3 How ClinOleic is given
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- 5 How ClinOleic is stored
- 6 Contents of the pack and other information

Throughout this leaflet ClinOleic 20% will be called ClinOleic.

1 What ClinOleic is and what it is used for

ClinOleic is an emulsion of olive oil (80%) and soya bean oil (20%) for infusion. ClinOleic is a milky looking liquid that is sterile (sometimes called a sterile emulsion). It contains:

- a source of energy, and
- some fats called essential fatty acids.

ClinOleic is used to give you food straight into your blood, when you cannot take enough food by your mouth. This method of feeding (parenteral nutrition) is used when food and drink cannot be taken in through the digestive system for medical reasons.

It is usually given with other things such as sugars (carbohydrates) and the building blocks for protein (called amino acids).

2 What you need to know before you are given ClinOleic

ClinOleic must not be given if you:

- are allergic (hypersensitive) to the active substances (egg, soybean or peanut protein) or to any of the other ingredients (see section 6, "Further information" at the end of this leaflet). Signs of an allergic reaction include being short of breath, wheezing, rash, itching or swelling of the face and lips,
- have a problem with the way your body handles fat, especially if tests show that you have a high amount of fat in your blood,
- have problems with your kidneys (lipod nephrosis) or inflammation of the pancreases (acute pancreatitis) if accompanied by high levels of fat in your blood.

Do not use ClinOleic if any of the above apply to you. If you are not sure talk to your doctor or nurse before using ClinOleic.

Your doctor will take special care with ClinOleic if:

Special clinical monitoring is required at the start of any infusion into your veins (intravenous infusion).

The infusion will be stopped immediately if you have any sign of allergic reaction. Signs include sweating, fever, chills, headache, skin rash, dyspnoea (difficulty to breathe). This medicinal product contains soya-bean oil and egg phospholipids. Soybean and egg proteins may cause hypersensitivity reactions. Cross-allergic reactions between soybean and peanut proteins have been observed.

Certain medications and illnesses can increase the risk of developing infection or sepsis (bacteria in the blood). There is a particular risk of infection or sepsis when a tube is placed in your vein. Your doctor will carefully watch you for any signs of infection.

Your doctor should be aware of:

- severe conditions affecting how your body handles sugars, fats, proteins or salt (metabolic disorders)
- a severe blood infection (sepsis)
- a severe liver disease
- a blood clotting (coagulation) disorder

If you are not sure if any of the above apply to you, talk to your doctor or nurse before being given ClinOleic.

Special care with use in children (paediatric use)

ClinOleic is suitable for use in young children if its use is monitored carefully.

When used in neonates and children below 2 years of age, the solution (in bags and administration sets) should be protected from light exposure until administration is completed. Exposure of Clinoleic to ambient light, especially after admixtures with trace elements and/or vitamins, generates peroxides and other degradation products that can be reduced by protection from light exposure.

Using other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

The olive and soybean oils present in ClinOleic contain vitamin K. This does not normally affect blood thinning medicines (anticoagulants) like coumarin. However, if you take anticoagulant medicines you should tell your doctor.

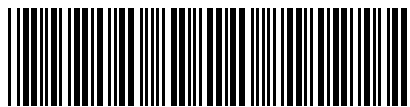
Pregnancy and breast-feeding

If you are pregnant think you might be pregnant, or are breastfeeding, tell your doctor. He or she will decide if you can be given ClinOleic.

3 How ClinOleic is given

ClinOleic will be given to you by a healthcare professional.

- Your doctor will decide how much you will need, the rate it is given to you and for how long.
- This will depend on the amount of nutrition you need and the reason you are being given ClinOleic.
- You will usually be given ClinOleic an infusion or drip through a plastic tube which will be into a vein, usually in your chest.
- Any other medicines or blood that you might need will not be given through this tube.
- When used in neonates and children below 2 years of age, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 2).



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If you are given more ClinOleic than you should

An overdose can cause a reduction in your body's ability to remove lipids from ClinOleic (fat overload syndrome). Your doctor will stop giving you ClinOleic or reduce the amount you are given until the level of fats in your blood returns to normal (see also section 4. Possible side effects).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, ClinOleic can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

If you notice any abnormal signs at the beginning of the infusion tell your doctor or nurse straightaway and your treatment will be stopped immediately. These signs include sweating, chills, headache and breathing difficulty

Other side effects have been noticed, occurring more or less frequently:

The following side effects are common and could affect 1 to 10 users in 100:

- Feeling sick (nausea), being sick (vomiting)
- Decrease of blood pressure
- Increased of sugar level in blood (hyperglycaemia)
- Decreased in blood protein levels (hypoproteinemia)
- Increased level of fats or triglycerides in the blood (hyperlipidaemia, blood triglycerides increased)
- Swelling of the belly (abdominal distension)
- Yellowing of the skin and eyes caused by gall-bladder problems or increased levels of bilirubin
- Muscle spasms
- Abnormal liver function test results

The following side effects are uncommon and could affect 1 to 10 users in 1,000:

- Decrease in the number of white blood cells that could lead to an infection which lasts longer, is more severe, or occurs more often than usual
- Failure of the blood circulatory system (circulatory collapse)
- Decreased blood pressure (hypotension)
- Hot flush
- Difficulty breathing
- Pain and discomfort around the stomach area (epigastric discomfort)
- Inflammation of the liver which can cause jaundice, weight loss and malaise
- Back pain
- Chills
- Increased level of enzymes from the pancreas

The following side effects have also been reported at an unknown frequency:

- Longer bleeding or easy bruising
- Swelling of the gallbladder
- Gall stones
- Itching sensation (pruritus)

If you have a reduced ability to remove the lipids contained in ClinOleic, this may result in a "fat overload syndrome". It may cause a sudden worsening in your clinical condition. Fat overload syndrome can result in:

- fever
- pale colour of the skin
- prolonged bleeding and bruising
- yellowing of the skin and the eyes

All of these symptoms are usually reversible when the infusion is stopped.

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

www.mhra.gov.uk/yellowcard

5 How ClinOleic is stored

- Keep this medicine out of the sight and reach of children.
- When used in neonates and children below 2 years of age, the solution (in bags and administration sets) should be protected from light exposure until administration is completed (see section 2).
- Do not store above 25°C. Do not freeze.
- Store in protective overwrap.
- Do not use ClinOleic after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- ClinOleic must not be used if the container is damaged or the emulsion is not evenly milky.
- The solution should only be used once. Any leftover solution should not be reconnected and should be disposed of by your healthcare professional.

6 Contents of the pack and other information

What ClinOleic contains

- The active substances are refined olive oil (80%) and refined soybean oil (20%) making up 200 g in 1000 ml of emulsion
- The other ingredients are glycerol, egg phospholipids, sodium oleate and sterile water (called 'water for injections'). It may also contain very small amounts of sodium hydroxide. This can be used to modify the acid level of ClinOleic.

What ClinOleic looks like and contents of the pack

ClinOleic is supplied as an emulsion for infusion (slow injection or drip) in a plastic bag container in a plastic overwrap which contains either 100 ml, 250 ml, 350 ml or 500 ml of emulsion. These pack sizes may not all be marketed. A 1000 ml volume is also available, for pharmacy use only.

An oxygen absorber/ oxygen indicator sachet is included inside the overwrap. Before opening the overwrap, the colour of the oxygen indicator affixed to the oxygen absorber should be checked. It should match the reference colour printed next to the OK symbol and shown in the printed area of the indicator label. The sachet should be disposed of after removing the overwrap.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is:

Baxter Healthcare Ltd

Caxton Way
Thetford
Norfolk
IP24 3SE

Send all enquiries to this address.

ClinOleic is made at:

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Belgium

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For information about ClinOleic or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: 01635 206345.

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