

OLIMEL / PeriOLIMEL

Emulsion for Intravenous Infusion

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about OLIMEL/PeriOLIMEL. It does not contain all of 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 using OLIMEL/PeriOLIMEL against the benefits he or she may expect it will have for you.

If you have any concerns about being administered this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What OLIMEL/PeriOLIMEL is used for and how it works

OLIMEL/PeriOLIMEL is a sterile mixture of fat (soya oil and olive oil), amino acids and glucose (with/without electrolytes depending on the formulation). It is used as a source of energy, maintaining the nitrogen/energy balance and correcting essential fatty acids deficiency. It is given as an infusion directly into your veins. OLIMEL/PeriOLIMEL is intended to provide you with nourishment (essential fatty acids, proteins, glucose) whilst you are unable to consume food by mouth.

Before you are given OLIMEL/PeriOLIMEL

OLIMEL/PeriOLIMEL should not be given to you if:

- you have had an allergic reaction to egg or soya proteins, peanut protein, corn/corn products or to any of the active or inactive ingredients (listed at the end of this leaflet).
- you have any of the following medical conditions:
 - problems in processing amino acids (congenital abnormalities of amino acid metabolism)
 - severe problems metabolising/breaking down fat resulting in abnormally high blood fat levels (severe hyperlipidaemia or hypertriglyceridaemia)
 - abnormally high blood sugar levels (severe hyperglycaemia)
 - abnormally high blood levels of the electrolytes - sodium, potassium, magnesium, calcium and/or phosphorus.
- after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

OLIMEL/PeriOLIMEL should not be used for newborn babies and children less than 2 years old.

Tell your doctor if:

- you are pregnant or plan to become pregnant or are breast-feeding
- you have any heart, lung, liver or kidney problems, an infection, metabolic acidosis (too much acid in the blood), diabetes, bleeding disorders, anaemia and/or high level of fat/lipids in the blood (hyperlipidaemia)

- you are taking any medicines, including any that you buy from your pharmacy (with/without a prescription), supermarket or health food shop (e.g. dietary/nutritional supplements).

Ask your doctor if you have any questions about OLIMEL/PeriOLIMEL.

How is OLIMEL/PeriOLIMEL to be given

How much will be given:

Your doctor will determine the amount of OLIMEL/PeriOLIMEL. Your doctor will regularly monitor your condition and test your blood during treatment to ensure that you receive the appropriate amount of OLIMEL/PeriOLIMEL.

How will it be given?

OLIMEL/PeriOLIMEL is given as a slow continuous infusion into a central vein, under the supervision of a health care professional (doctor or trained nurse). PeriOLIMEL may be given through a peripheral vein. The recommended duration of the infusion is between 12 and 24 hours.

In case of overdose

As OLIMEL/PeriOLIMEL will be given to you by a doctor/nurse, it is unlikely that you will be given an overdose. However, if you are given too much OLIMEL/PeriOLIMEL or it is infused too quickly, you may feel nausea, vomiting, unwell and shivering. Your doctor will regularly monitor your condition and test your blood and urine parameters to prevent an overdose. Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

Side Effects

Most people do not experience side effects. However, as with most medicines, OLIMEL/PeriOLIMEL can sometimes cause unwanted side effects. These may include fast heart rate, stomach pain, diarrhoea, nausea, loss of appetite, fever and/or chills. Tell your doctor or pharmacist as soon as possible if you have any of these symptoms or do not feel well while you are on OLIMEL/PeriOLIMEL.

Tell your doctor or other health care professional immediately, if you notice any of the following:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- abdominal pain, diarrhoea and nausea
- loss of appetite
- reaction at injection site

These may be symptoms of an allergic reaction. You may need urgent medical attention.

Product Description

What do OLIMEL/PeriOLIMEL look like?

OLIMEL/PeriOLIMEL is presented in a plastic bag composed of 3 compartments to be mixed before use. The reconstituted mixture is a milky white solution. There are six different strengths: PeriOLIMEL N4-600E, OLIMEL N5-860E, N7-960, N7-960E, N9-840 and N9-840E, which contain different amounts of the nutrients.

Each formulation is available in the following pack sizes:

- PeriOLIMEL N4-600E - 1000 mL, 1500 mL, 2000 mL & 2500 mL
- OLIMEL N5-860E - 1500 mL, 2000 mL & 2500 mL
- OLIMEL N7-960 - 1000 mL, 1500 mL & 2000 mL
- OLIMEL N7-960E - 1000 mL, 1500 mL & 2000 mL
- OLIMEL N9-840 - 1000 mL, 1500 mL & 2000 mL
- OLIMEL N9-840E - 1000 mL, 1500 mL & 2000 mL

Not all formulations and pack sizes may be marketed.

Ingredients:

OLIMEL/PeriOLIMEL contains the following active ingredients:

- 17 amino acids: alanine, arginine, aspartic acid, glutamic acid, glycine, histidine, isoleucine, leucine, lysine, methionine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine and valine
- Refined olive oil and refined soya oil
- Glucose

In addition, PeriOLIMEL N4-600E and OLIMEL N5-860E, N7-960E and N9-840E contain the following electrolytes:

- Calcium chloride
- Magnesium chloride
- Potassium chloride
- Sodium acetate
- Sodium glycerophosphate hydrate

OLIMEL/PeriOLIMEL (all formulations) also contains the following inactive ingredients:

- Egg lecithin (purified egg phosphatide)
- Glycerol
- Sodium oleate
- Sodium hydroxide
- Glacial acetic acid
- Hydrochloric acid
- Water for injections

Storage Conditions

OLIMEL/PeriOLIMEL should be stored in overpouch at a temperature below 25°C. Do not freeze.

Where to go for further information?

You can get more information about any aspect of your treatment from your doctor or pharmacist.

Name and Address of Sponsor

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

Australian Registration numbers:

- PeriOLIMEL N4-600E - AUST R 197419
- OLIMEL N5-860E - AUST R 197417
- OLIMEL N7-960 - AUST R 197421
- OLIMEL N7-960E - AUST R 197418
- OLIMEL N9-840 - AUST R 197416
- OLIMEL N9-840E - AUST R 197420

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