

precursor in the synthesis of a special class of eicosanoids (prostaglandins, thromboxanes, leukotrienes, and other lipid mediators). Increased synthesis of these eicosapentaenoic acid-derived mediator substances may help promote antiaggregatory, and anti-inflammatory effects, and is associated with immunomodulatory effects.

The glycerol contained in Omegaven is designed for use in energy production via glycolysis or is re-esterified together with free fatty acids in the liver to form triglycerides.

Omegaven also contains egg phospholipids, which are hydrolysed or incorporated into the cell membranes, where they are essential for the maintenance of membrane integrity.

Pharmacokinetic properties

The lipid particles infused with Omegaven are similar in size and elimination to physiological chylomicrons. In healthy male volunteers, a triglyceride half-life for Omegaven of 54 minutes has been calculated.

- irregularities of the blood - anaemia, low white bloodcell count
- bleeding and a tendency to bleed
- altered liver function tests
- fever
- high lipid levels in the blood (hyperlipidaemia)
- headache, stomach pains, fatigue
- a high sugar level in the blood (hyperglycemia)

Should any of these side effects occur your infusion may be stopped or if necessary, continued at a reduced dose.

Overdose leading to **fat overload syndrome** may occur:

This might happen when your body has problems using fat, because of having too much Omegaven. It may also happen because of a sudden change in your condition (such as kidney problems or infection). Possible signs are fever, problems in various organs of the body and coma. All these will usually disappear when you stop having the infusion.

A severe overdosage of Omegaven without administration of a carbohydrate solution at the same time, may lead to metabolic acidosis.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE OMEGAVEN

Keep out of the reach and sight of children.

Do not use Omegaven after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Omegaven contains

The active substances are

100 ml emulsion contains:

Highly refined fish oil	10.0 g
Containing:	
eicosapentaenoic acid (EPA)	1.25 - 2.82 g
docosahexaenoic acid (DHA)	1.44 - 3.09 g
dl- α -Tocopherol (as an antioxidant)	0.015 - 0.0296 g

Glycerol	2.5 g
Purified egg phosphatide	1.2 g

The other ingredients are

sodium oleate, sodium hydroxide, water for injections.

<i>Total energy:</i>	470 kJ/100 ml = 112 kcal/100 ml
<i>pH value:</i>	7.5 to 8.7
<i>Titration acidity:</i>	< 1 mmol HCl/l
<i>Osmolality:</i>	308-376 mosm/kg

What Omegaven looks like and contents of the pack

Emulsion for infusion, white homogenous emulsion
Glass vials (type II, colourless) and bromobutyl rubber stoppers.
Pack sizes: 1 x 50 ml, 10 x 50 ml, 1 x 100 ml, 10 x 100 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation

Fresenius Kabi Deutschland GmbH
61346 Bad Homburg v.d.H. Germany

Manufacturer

Fresenius Kabi Austria GmbH
8055 Graz, Austria

This leaflet was last approved in: July/2012

M0xxxxxx/xx EXP

PACKAGE LEAFLET: INFORMATION FOR THE USER

Omegaven

Emulsion for infusion

Read all of this leaflet carefully before you start using this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet:

1. What Omegaven is and what it is used for
2. Before you receive Omegaven
3. How you are given Omegaven
4. Possible side effects
5. How Omegaven is stored
6. Further information

1. WHAT OMEGAVEN IS AND WHAT IT IS USED FOR

Omegaven provides energy and omega-3 fatty acids derived from fish oil into your bloodstream when oral nutrition is impossible, insufficient or not recommended.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE OMEGAVEN

Omegaven will not be used

- if you are allergic (hypersensitive) to fish or egg protein or any of the ingredients of Omegaven. For symptoms of an allergic reaction please refer to section 4.
- if you have severe bleeding disorders
- if you have collapsed or are in shock
- if you have recently had a severe heart attack

- if you recently had a severe stroke,
- if you been told that you have a severe embolism (blockage of the artery)
- if you suffer from low potassium level (hypokalaemia),
- if you have too much fluid in your body (hyperhydration)
- if you are dehydrated with low levels of sodium
- if your metabolism is unstable
- if you have acidosis (where the acid levels of your body fluids and tissues become too high)
- if you suffer from serious liver or kidney insufficiency

Due to limited experience, Omegaven should not be given to premature infants, newborns, infants and children up to 11 years. This medicine will not be given to you if you are in an uncertain state of unconsciousness.

Take special care with Omegaven.

Inform your doctor if you suffer from:

- diabetes (type 1 and 2 diabetes)
- a condition where your body has problems using fat properly

Inform your doctor if you are taking medicines used in anticoagulation therapy to thin your blood. If you are taking blood thinning medicines (anticoagulants) your doctor may want to do regular blood tests to make sure that your therapy is well controlled.

Your serum triglyceride level may be monitored daily and its concentration should not exceed 3 mmol/l during the infusion of fat emulsions.

Taking other medicines

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

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. There is no evidence on the safety of this medicine during pregnancy or breastfeeding.

This medicine should be used during pregnancy and breastfeeding only if strictly necessary.

3. HOW TO USE OMEGAVEN

You will receive your medicine by infusion.

Your doctor will decide on the correct dose and infusion rate for you. It will depend on your body weight in kilograms and your body's ability to use fat. The infusion will be given to you in the hospital by a healthcare professional.

The duration of administration should not exceed 4 weeks.

Dose

Daily dose:

1 ml up to max. 2 ml Omegaven/kg body weight = 0.1 g up to max. 0.2 g fish oil/kg body weight = 70 ml up to max. 140 ml Omegaven for a patient with a body weight of 70 kg.

Maximum infusion rate:

The infusion rate should not exceed 0.5 ml Omegaven/kg body weight/hour corresponding to 0.05 g fish oil/kg body weight/hour.

The maximum infusion rate should be strictly adhered to, otherwise a severe increase in the serum triglyceride concentration can be observed.

Omegaven should be administered simultaneously with other fat emulsions. On the basis of a recommended total daily lipid intake of 1 - 2 g/kg body weight, the fish oil portion from Omegaven should constitute 10-20% of this intake.

If you receive too much Omegaven

It is very unlikely that you will receive more infusion than you should as your doctor or nurse will monitor you during the treatment. For the effects of an overdose see section 4 "Possible side effects". If you believe that you have received too much Omegaven inform your doctor or nurse immediately. If this happens the infusion will be stopped immediately. It may be possible to continue with a reduced dosage. These symptoms will usually disappear on reducing the rate or stopping the infusion.

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

4. POSSIBLE SIDE EFFECTS

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

Undesirable side effects observed during the administration of Omegaven

Rare (affects 1 to 10 users in 10,000)	<ul style="list-style-type: none"> • Prolonged bleeding time and impaired blood clotting • A fishlike taste in your mouth
--	---

Undesirable side effects observed during the administration of fat emulsions

Uncommon (affects 1 to 10 users in 1,000)	<ul style="list-style-type: none"> • Abdominal pain, nausea (feeling sick), vomiting • Rise in body temperature, shivering, chills, tiredness • Hypertriglyceridaemia (excess fats in the blood) • Headache
Very rare (affects less than 1 user in 10,000)	<ul style="list-style-type: none"> • Anaphylactic reaction (severe allergic-like reaction characterized by a considerable increase of body temperature and difficulties in breathing) • Rash, urticaria (nettle rash i.e. a bumpy and itchy like rash appears on your body) • Circulatory effects - e.g. hypertension or hypotension (high or low blood pressure) • Abnormal blood values (thrombocytopenia, haemolysis, reticulocytosis) • Transient (temporary) increase in liver function test • Priapism (persistent, usually painful erection)

Possible signs of metabolic overload must be observed. The cause may be genetic (Individual differences in metabolism) or from previous illnesses. However, this has been observed mainly with the use of cottonseed oil emulsions.

Metabolic overload might give the following symptoms:

- enlargement of the liver (hepatomegaly) with or without jaundice (yellowing of the skin)
- a change or reduction of some coagulation parameters (e.g. bleeding time, coagulation time, prothrombin time, platelet count)
- enlargement of the spleen (splenomegaly)

The following information is intended for medical or healthcare professionals only:

The usual daily dose is:

1 ml up to max. 2 ml Omegaven/kg body weight = 0.1 g up to max. 0.2 g fish oil/kg body weight = 70 ml up to max. 140 ml Omegaven for a patient with a body weight of 70 kg.

The infusion rate should not exceed 0.5 ml Omegaven/kg body weight/hour corresponding to 0.05 g fish oil/kg body weight/hour.

The maximum infusion rate should be strictly adhered to, otherwise a severe increase in the serum triglyceride concentration can be observed.

Omegaven should be administered together with other fat emulsions. On the basis of a recommended total daily lipid intake of 1 - 2 g/kg body weight, the fish oil portion from Omegaven should constitute 10 - 20% of this intake.

Method of administration:

For infusion via central or peripheral vein. Containers should be shaken before use. Use only if the emulsion is homogeneous and the container is undamaged.

Non-phthalate containing equipment should be used for administration wherever possible. Any portions of contents as well as mixtures remaining after use should be littered.

Incompatibilities

When Omegaven is to be administered with other infusion solutions (e.g. amino acid solutions, carbohydrate solutions) via a common infusion line (by-pass, y-tube), the compatibility (tolerance) of the solutions/emulsions used must be ensured.

Incompatibilities may occur through the addition of polyvalent cations, e.g. calcium, especially when combined with heparin (anticoagulant).

Duration of administration

The duration of administration should not exceed 4 weeks.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Emulsion for parenteral nutrition

ATC-Code: B05BA

The long-chain omega-3 fatty acids in Omegaven are partly incorporated in plasma and tissue lipids. Docosahexaenoic acid is an important structural element in membrane phospholipids, while eicosapentaenoic acid is a