

DATA SHEET

NAME OF MEDICINE

Omegaven (fish oil – highly refined 10%, glycerol 2.5% and egg lecithin 1.2 %)
Emulsion for Infusion

PRESENTATION

Omegaven is white homogenous emulsion and it contains the following:

Content

Ingredients	g/100 mL
Highly refined fish oil	10.0
containing:	
Eicosapentaenoic acid (EPA)	1.25-2.82
Docosahexaenoic acid (DHA)	1.44-3.09
dl- α -tocopherol (as antioxidant)	0.015-0.0296
Glycerol	2.5
Egg lecithin	1.2
Total energy per 100 mL	470 kJ(112 kcal)
pH value	7.5 to 8.7
Titration acidity	< 1 mmol HCl/L
Osmolality	308-376 mOsm/kg water

USES

Actions

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

The glycerol contained in Omegaven is intended 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 lecithin, which are hydrolysed or incorporated into the cell membranes, where they are essential for the maintenance of membrane integrity.

Pharmacokinetics

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.

Preclinical Safety data

Preclinical data reveal no special hazard for humans based on conventional studies of acute and repeated dose toxicity, safety pharmacology and genotoxicity. No fertility studies have been conducted.

Sensitisation tests

In a test in Guinea pigs (Maximisation test) Omegaven showed moderate dermal sensitisation. A systemic antigenicity test gave no indication of evidence of anaphylactic potential of Omegaven.

INDICATIONS

For use as a fraction of the lipid emulsion component for total parenteral nutrition, providing supplements of long chain omega-3-fatty acids especially eicosapentanoic and docosahexanoic acid when oral or enteral nutrition is impossible, insufficient or contraindicated.

DOSAGE AND ADMINISTRATION

Daily dose:

1 mL up to maximum of 2 mL Omegaven/kg body weight

= 0.1 g up to a maximum of 0.2 g fish oil/kg body weight.

= 70 mL up to 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 bodyweight, 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.

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 of the solutions/emulsions used must be ensured.

Duration of administration

The duration of administration should not exceed 4 weeks

CONTRAINDICATIONS

- Impaired lipid metabolism
- Severe haemorrhagic disorders
- Unstable diabetes mellitus

Certain acute and life-threatening conditions such as:

- collapse and shock

- recent cardiac infarction
- stroke
- embolism
- undefined coma status

Due to lack of experience Omegaven should not be administered in patients with severe liver or renal insufficiency.

Omegaven should not be used in premature infants, newborns, infants and children due to limited experience.

General contra-indications for parenteral nutrition:

- hypokalaemia
- hyperhydration
- hypotonic dehydration
- unstable metabolism
- acidosis

Omegaven should not be administered to patients known to be allergic to fish or egg protein.

WARNINGS

The serum triglyceride level should be monitored daily. Checks of blood glucose profiles, acid base metabolism, serum electrolytes, fluid balance, blood count and bleeding time in patients treated with anticoagulants must be carried out regularly. The serum triglyceride concentration should not exceed 3 mmol/L during the infusion of fat emulsions.

PRECAUTIONS

Please see Warnings.

Use in Pregnancy and Lactation (Category B2)

There is no evidence on the safety of this medicine during pregnancy or breastfeeding. This medication should not be used during pregnancy and breastfeeding.

Interaction with other drugs

The infusion of Omegaven can cause a prolonged bleeding time and an inhibited platelet aggregation. Therefore, Omegaven should be administered with caution to patients requiring anticoagulant therapy even with regard to a possible reduction of anticoagulants.

Compatibility with other drugs

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

Omegaven may be aseptically mixed with fat emulsions as well as fat-soluble vitamins. Chemical and physical in-use stability of mixtures containing Omegaven has been demonstrated for 24 hours at 25°C and data is available from the manufacturer. From a microbiological point of view, mixtures with fat emulsions or fat emulsions containing fat-soluble vitamins should be used immediately. If not used immediately, in-use storage time and conditions prior to use are the responsibility of

the user. Only if compounding has taken place in controlled and validated aseptic conditions can storage conditions be based on the manufacturers stability data. From a microbiological point of view, mixtures compounded in uncontrolled and unvalidated conditions should normally be used within 24 hours, including the infusion time (see Instructions for use/handling).

Omegaven is unlikely to produce an effect on the ability to drive or use machinery.

ADVERSE REACTIONS

The infusion of Omegaven can lead to a prolonged bleeding time and an inhibited platelet aggregation. In rare cases patients may experience a fishy taste.

Undesirable effects observed during the administration of fat emulsions:

- slight rise in body temperature
- heat sensation and/or cold sensations
- chill
- flush or cyanosis
- lack of appetite, nausea, vomiting
- dyspnoea
- headache, pain in the chest, back and loins, bone-pain
- priapism (in very rare cases)
- increase or decrease in blood pressure
- anaphylactic reactions (e.g. erythema)

Possible signs of metabolic overload must be observed. The cause may be genetic (individually different metabolisms) and with respect to different previous illness with varying rapidity and following different doses, but has been observed mainly with the use of cottonseed oil emulsions.

Metabolic overload might give the following symptoms:

- hepatomegaly with or without icterus
- a change or reduction of some coagulation parameters (e.g. bleeding time, coagulation time, prothrombin time, platelet count)
- splenomegaly
- anaemia, leucopenia, thrombocytopenia
- bleedings and tendency to bleed
- pathological liver function tests
- fever
- hyperlipidaemia
- headache, stomach pains, fatigue
- hyperglycaemia

Should these side-effects occur or should the triglyceride level during lipid infusion rises above 3 mmol/L, the lipid infusion should be stopped or, if necessary, continued at a reduced dosage.

OVERDOSAGE

Overdose leading to fat overload syndrome may occur when the triglyceride level during lipid infusion rises above 3 mmol/L, acutely, as a result of too rapid infusion rate, or chronically at recommended rates of infusion in association with a change in the patient's clinical condition e.g. renal function impairment or infection.

Overdosage may lead to side-effects (see Adverse Reactions).

In these cases, the lipid infusion should be stopped or, if necessary, continued at a reduced dosage. The administration of fat has to be stopped if a marked increase in blood glucose levels occurs during infusion of Omegaven. A severe overdosage of Omegaven without simultaneous administration of a carbohydrate solution, may lead metabolic acidosis.

PHARMACEUTICAL PRECAUTIONS

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Instructions for use/handling

To be used immediately after breaking the vial seal. Containers should be shaken before use. Use only if the emulsion is homogenous and the container is undamaged. Non-phthalate containing equipment should be used for administration wherever possible.

When simultaneously administered with other fat emulsions admixed or diluted before administration (see Incompatibilities)

Omegaven should be used with sterile transfer equipment immediately after opening. Any portions of contents as well as mixtures remaining after use should be discarded.

STORAGE

Store below 25°C. Do not freeze.

MEDICINE CLASSIFICATION

General Sale Medicine

PACKAGE QUANTITIES

50 mL or 100 mL glass bottles available in packs of 10 bottles.

NAME AND ADDRESS

Sponsor

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