Omegaven® emulsion for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION

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 antioxidant) 0.015 - 0.0296 g. Glycerol 2.5 g, Purified egg phosphatide 1.2 g.

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

Therapeutic indications

Parenteral nutrition supplementation with long chain omega-3-fatty acids, especially eicosapentaenoic and docosahexaenoic acid, when oral or enteral nutrition is impossible, insufficient or contraindicated.

Posology and method of administration

Posology

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.

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 (eg amino acid solutions, cabohydrate 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

Severe haemorrhagic disorders.

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
- acidoses

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

Special warnings and precautions for use

Omegaven should be given with caution to patients with an impaired lipid metabolism and uncontrolled diabetes mellitus.

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.

Undesirable effects

Undesirable effects observed during the administration of Omegaven:
Investigations: Rare (≥ 1/10,000, <1/1,000): The infusion of Omegaven can lead to a prolonged bleeding time and an inhibited platelet aggregation. Clinically relevant abnormalities have not been observed. *Gastrointestinal Disorders: Rare (≥ 1/10,000, <1/1,000)*: fishy taste

Undesirable effects observed during the administration of fat emulsions:
Uncommon: ≥ 1/1,000, <1/100; Rare: ≥ 1/10,000, <1/1,000; Very rare: < 1/10,000. Blood and lymphatic system disorders: very rare: thrombocytopenia, haemolysis, reticulocytosis. Gastrointestinal disorders: uncommon: abdominal pain, nausea, vomiting. General disorders and administration site conditions: uncommon: rise in body temperature, shivering, chills, tiredness. Immune system disorders: very rare: anaphylactic reaction. Investigations: very rare: transient increase in liver function test. Metabolism and nutrition disorders: uncommon: hypertriglyceridaemia. Nervous system disorders: uncommon: headache. Reproductive system and breast disorders: very rare: priapism. Skin and subcutaneous tissue disorders: very rare: rash, urticaria. Vascular disorders: very rare: circulatory effects (e.g. hyper/hypotension).

Thrombocytopenia has been reported in association with prolonged treatment with fat emulsions in infants. Transient increase in liver function tests after prolonged intravenous nutrition with or without fat emulsions have also been noted. The reasons are not clear at present. Possible signs of metabolic overload must be observed. The cause may be genetic (individually different metabolisms) and with respect to different previous illnesses 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, hyperglycemia. Should these side-effects occur or should the triglyceride level during lipid infusion rise above 3 mmol/l, the lipid infusion should be stopped or, if necessary, continued at a reduced dosage.

Date of Revision of the Text

23 April 2010