

Omegaven

Emulsion for infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Omegaven. It does not contain all 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 given Omegaven against any benefits they expect it will have for you.

Please read this leaflet carefully before given Omegaven. If you have any questions or are unsure about anything, please ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What Omegaven is used for

Omegaven is a sterile fat emulsion, which provides your body with energy and fatty acids. The active ingredient in Omegaven is fish oil. It also contains other ingredients like egg lecithin which is isolated from egg yolk, glycerol and water for injections.

Omegaven provides the energy and fatty acids in patients who require intravenous nutrition.

Before you are given Omegaven

You should NOT be given Omegaven if you answer YES to any of the following:

- You have an inability to break down fats

- You are suffering from a very serious problem with your blood circulation.
- You have too much sugar in your blood or diabetes which is not under control.
- You are suffering from a severe unstable medical condition.
- You are experiencing a sudden decrease in blood pressure.
- You have certain untreated heart problems.
- You have severe liver failure.
- You have severe kidney failure.
- You are under 12 years of age.
- You have too much fluid in your body.
- You have an allergy to any of the ingredients contained in Omegaven as listed at the end of this leaflet e.g fish or egg protein.
- You have too much acid in your blood, also called metabolic acidosis.
- There is not enough water content in your body.

If you are not sure whether any of these apply to you, check with your doctor.

Before you start to take it

If the answer to any of the following questions is YES, you should tell your doctor BEFORE given Omegaven.

- Are you pregnant or trying to become pregnant?
- Are you breastfeeding?
- Are you a diabetic?

- Are you taking anticoagulants (medicines for preventing blood clotting)?
- Are you taking any other medicines including any that you buy without a prescription from your pharmacy, supermarket or health food shop. These medicines may affect the action of Omegaven or may affect how well Omegaven works.

How to take Omegaven

The dose of Omegaven which you will require will be determined by your doctor or pharmacist. Your doctor will supervise your treatment with Omegaven.

Side Effects

Omegaven, like all other nutrient solutions which are given intravenously, may cause side effects in some people. All the side effects associated with Omegaven may not yet have been detected.

The common side effects are slight rise in your body temperature, heat sensation and/or cold sensations, shivering, flush, lack of appetite, nausea, vomiting and headache.

Other rare side effects that have occurred during treatment with Omegaven are lower back pain, pain in the chest and loins, bone pain, increase or decrease in blood pressure, sudden allergic skin reactions e.g rash, breathing difficulties (rapid breathing, shortness of breath) and persistent

painful erection of the penis which occurs without sexual arousal.

If you have these or any other side effects during treatment, tell your doctor.

In case of overdose

This rarely happens as Omegaven is administered under the care of a trained professional in a hospital or clinic setting. The symptoms of overdose are similar to the side effects. These symptoms are usually reversible if the infusion of the fat emulsion is discontinued.

If you think you or anyone else have been given too much Omegaven, telephone your doctor or contact the Poisons Information Centre - New Zealand: 0800 764 766.

Storage

The expiry date of Omegaven is on the label of the pack. Omegaven should not be used if the expiry date has passed.

Omegaven should be stored below 25°C, but not frozen. Do not use Omegaven if it has been frozen.

The contents of each bottle of Omegaven are for single infusion only. Any unused Omegaven should be discarded. Do not use Omegaven if it is discoloured.

Product Description

Omegaven is a white milky emulsion which is supplied in 50mL or 100mL glass bottles. It comes in a carton pack of 10 bottles.

Ingredients

The active substances in grams of 100 mL correspond to:

Highly refined fish oil containing	10.0
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

Omegaven also contains the excipients sodium hydroxide, sodium oleate and water for injections.

Omegaven does not contain any preservative.

Omegaven does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Omegaven supplies the following:
Energy: 470 kJ(112 kcal)/100mL
Osmolality: 308-376 mOsm/kg water
pH: 7.5 to 8.7

Further Information

More detailed information is available from your doctor or pharmacist. Therefore, if you have any concerns about the information or about Omegaven ask your doctor or pharmacist.

Sponsor

Fresenius Kabi New Zealand Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892

Date of information

This leaflet was prepared in January 2017.