

Lipidem 200 mg/ml

emulsion for infusion

Medium-chain triglycerides / soya-bean oil, refined / omega-3-acid triglycerides

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lipidem is and what it is used for
2. What you need to know before you are given Lipidem
3. How to use Lipidem
4. Possible side effects
5. How to store Lipidem
6. Content of the pack and other information

1. What Lipidem is and what it is used for

Lipidem is an emulsion of oils in water. The oils contained in Lipidem provide energy and contain essential fatty acids that are needed for your body to grow or recover.

Lipidem is used to provide fat to patients needing to be fed by an intravenous drip, because they are unable to eat food normally or the normal intake is not enough.

Lipidem is indicated in adults, preterm and term neonates, infants and toddlers, children and adolescents.

2. What you need to know before you are given Lipidem

Lipidem must NOT be used

if one or more of the following conditions are present:

- if you are allergic to egg, fish, peanut, or soya-bean protein or any of the other ingredients of this medicine (listed in section 6).
- abnormally high blood fat level (severe hyperlipidaemia characterised by hypertriglyceridaemia)
- conditions where the blood does not clot properly (severe coagulopathy)
- impaired bile flow (intrahepatic cholestasis)
- severe liver failure (severe hepatic insufficiency)
- severe kidney failure (severe renal insufficiency) without access to treatment with an artificial kidney (haemofiltration or dialysis)
- blocking of blood vessels by blood clots or fat (acute thromboembolic events, fat embolism)
- abnormally high level of acidic substances in the blood (acidosis)

Patients must generally not receive artificial nutrition via intravenous drip (parenteral nutrition)

if one or more of the following conditions are present:

- life-threatening blood circulation problems such as those that can occur if you are in a state of collapse or shock
- acute phase of heart attack (cardiac infarction) or stroke
- unstable metabolism, for example because of diabetes mellitus, infections involving the whole body (severe sepsis), or coma of unknown origin
- insufficient supply of oxygen to tissues
- disturbances of your body salt composition
- fluid deficit or excess water in the body
- water in the lungs (acute pulmonary oedema)
- severe heart failure (decompensated cardiac insufficiency)

Warnings and precautions

Talk to your doctor before you are given Lipidem.

Monitoring

- During infusion, the amount of fat (serum triglycerides) in your blood should be monitored by your doctor. If your blood fat values rises too high, your doctor may reduce the infusion speed or stop the infusion.
- While you receive this solution, your doctor should check your levels of fluids, blood salts and the acid-base balance. Your liver and kidney function and your blood clotting function should be monitored and blood cell counts should be performed.
- If you show signs of an allergic reaction – such as fever, shivering, rash, or breathing problems – when you receive this medicine, the infusion should be stopped immediately by your doctor.

Additional measures

- Before you receive this medicine any existing disorders of your body's fluid and salt content as well as disturbances of your acid-base balance will be corrected by your doctor.
- In addition to Lipidem you may receive a carbohydrate solution and an amino acid solution to prevent metabolic conditions where your blood becomes acidic (metabolic acidosis).
- To make your intravenous feeding complete, you may also receive carbohydrate solutions and amino acid solutions. The nursing staff may also take measures to ensure that your body's fluid, electrolyte, vitamin and trace element requirements are met.

Elderly patients

In some conditions your ability to use fat correctly may be impaired. Your doctor will keep in mind that some of these conditions are frequently associated with advanced age, e.g. impaired heart or kidney function.

Patients with heart or kidney problems

If you have heart or kidney problems, your doctor will be especially careful when giving you this medicine.

Patients with impaired lipid metabolism

In some conditions your ability to use fat correctly may be impaired and your blood fat values may be too high. Therefore, it is important that your doctor knows:

- if you have diabetes mellitus
- if you have an inflammation of the pancreas (pancreatitis)
- if you have impaired liver or kidney function (renal insufficiency, impaired hepatic function)
- if you have a reduced activity of the thyroid gland (hypothyroidism)
- if you have blood poisoning (sepsis)
- if you have a condition where you may have a combination of 3 or more of the following: an increase in fat around your abdomen, a decrease in "good cholesterol" (HDL-C), an increase in your blood fat, high blood pressure and an increase in your blood sugar (metabolic syndrome)

If your ability to use fat correctly is impaired, your doctor should monitor your blood fat (serum triglyceride) levels very closely.

Children and adolescents

In infants at risk of jaundice the blood fat (serum triglyceride) and bilirubin levels should be monitored by your doctor. It may become necessary for your doctor to adjust the daily fat doses.

During infusion this solution should be protected from the light of a phototherapy to decrease the formation of potentially harmful substances (triglyceride hydroperoxides).

Other medicines and Lipidem

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Lipidem may interact with some other medicines. Tell your doctor if you are taking or receiving certain medicines that prevent undesirable blood clotting, namely

- heparin
- coumarin products, for example warfarin.

It may be necessary to check the clotting of your blood by taking regular blood samples.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

Pregnancy

If you are pregnant you will receive this medicine only if the doctor considers it absolutely necessary for your recovery. There is no data about the use of Lipidem in pregnant women.

Breast-feeding

Breast-feeding is not recommended for mothers on parenteral nutrition.

Driving and using machines

You will receive this medicine in a controlled setting, i.e. a hospital or under any other kind of medical supervision, which normally excludes driving or using machines.

Lipidem contains sodium

Lipidem contains 2.6 mmol/l sodium. This should be taken into consideration by patients on a controlled sodium diet.

3. How to use Lipidem

Dosage

Your doctor will decide how much of this medicine you need and for how long you will require treatment with this medicine.

The daily doses will be adjusted to your needs, your age and your body weight. The doses are normally calculated on a "gram of fat per kg body weight" basis. Care will be taken that the doses and infusion rates used are correct for you, so your body's capacity to use the infused fat will not be exceeded.

How is Lipidem given?

Lipidem will be given by an intravenous drip as part of a feeding programme. For this purpose a tube (catheter) will be inserted into a vein, through which the fat emulsion can either be given separately or together with other fluids.

If you received more Lipidem than you should

If you have received too much Lipidem you may get abnormally high blood fat levels (hyperlipidaemia), your blood may become too acidic (metabolic acidosis) or you may suffer from a so-called "fat overload syndrome". For symptoms of the fat overload syndrome please see section 4 "Possible side effects".

If you have received too much Lipidem the infusion will be stopped immediately. The infusion will not be started again until you have recovered. It may be necessary for your doctor to adjust the daily fat doses. Your doctor will decide on any additional treatment.

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

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4. Possible side effects

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

The following side effects may be serious. If any of the following side effects occur, contact your doctor immediately, they will stop giving you this medicine:

- Very rare: may affect up to 1 in 10,000 people
- allergic reactions, for example skin reactions, shortness of breath, swelling of the lips, mouth and throat, difficulty breathing
- breathing problems (dyspnoea)
- bluish skin (cyanosis)

Other side effects include

- Very rare: may affect up to 1 in 10,000 people
- fat overload syndrome (see "Fat overload syndrome" below)
- increased tendency of your blood to clot (hypercoagulation)
- abnormally high blood fat levels (hyperlipidaemia)
- abnormally high blood sugar levels (hyperglycaemia)
- high levels of acidic substances in your blood (metabolic acidosis)
- decrease or increase in blood pressure
- drowsiness
- feeling sick, vomiting, loss of appetite
- headache
- flushing
- reddening of the skin (erythema)
- fever
- sweating
- feeling cold, chills

- Rare: may affect up to 1 in 1,000 people
- pain in the back, bones, chest and lumbar region

Not known: frequency cannot be estimated from the available data

- impaired bile flow (cholestasis)
- reduction of white blood cell count (leucopenia)
- reduction of blood platelet count (thrombocytopenia)

If you get any of these side effects, the infusion will be stopped.

Fat overload syndrome:

You might suffer from a "fat overload syndrome" if you have received too much Lipidem or when your body has problems using fat. Your body's ability to use fat might be influenced by a sudden change in your condition (due to renal problems or an infection). The symptoms are usually reversible if the infusion is stopped. A fat overload syndrome is characterised by the following symptoms:

- high blood fat levels (hyperlipidaemia)
- fever
- deposition of fat in the liver or other organs (fat infiltration)
- enlargement of the liver (hepatomegaly), which may sometimes be accompanied by jaundice (icterus)
- enlargement of the spleen (splenomegaly)
- reduction of red blood cell count (anaemia)
- reduction of white blood cell count (leucopenia)
- reduction of blood platelet count (thrombocytopenia)
- disorder of blood clotting (coagulation disorder)
- rupture of blood cells (haemolysis)
- increase in immature red blood cells (reticulocytosis)
- abnormal liver function tests
- loss of consciousness (coma)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lipidem

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and the outer carton. The expiry date refers to the last day of that month.

After first opening Lipidem should be used immediately.

Do not store above 25 °C.

Keep the container in the outer carton in order to protect from light. Do not freeze. Products that have been frozen must be discarded.

Do not use this medicine if you notice:

- large oil drops in the emulsion or two separate layers of fluid
- discoloration
- damage of the container or the closure.

6. Content of the pack and other information

What Lipidem contains

- The active substances in 1000 ml of Lipidem are:

Medium-chain triglycerides	100.0 g
Soya-bean oil, refined	80.0 g
Omega-3-acid triglycerides	20.0 g

This gives the following content of essential fatty acids per litre:

Linoleic acid (omega-6)	38.4 - 46.4 g
Alpha-linolenic acid (omega-3)	4.0 - 8.8 g
Eicosapentaenoic acid and docosahexaenoic acid (omega-3)	8.6 - 17.2 g

200 mg/ml (20%) correspond to total content of triglycerides.

Energy [kJ/l (kcal/l)]	7990 (1910)
Osmolality [mOsm/kg], approximately	410
Acidity or alkalinity (titration to pH 7.4) [mmol/l NaOH or HCl]	< 0.5
pH	6.5 - 8.5

- The other ingredients are glycerol, egg lecithin, all-rac- α -Tocopherol, ascorbyl palmitate, sodium oleate, sodium hydroxide (for pH adjustment) and water for injections.

What Lipidem looks like and contents of the pack

Lipidem is a milky-white, sterile oil-in-water emulsion for infusion (for administration by a venous drip).

It is supplied in glass bottles with rubber stoppers, pack sizes: 10 × 100 ml, 1 × 250 ml, 10 × 250 ml, 1 × 500 ml, 10 × 500 ml, 1 × 1000 ml, 6 × 1000 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen, Germany

Postal address

34209 Melsungen, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Lipidem Emulsion zur Infusion
Belgium:	Lipoplus 200 mg/ml
Czech Republic:	Lipoplus 20%
Germany:	Lipidem Emulsion zur Infusion
Denmark:	Lipidem
Estonia:	Lipidem
Spain:	Lipoplus 20%
Finland:	Lipoplus 200 mg/ml
France:	Lipidem 200 mg/ml
Hungary:	Lipoplus
United Kingdom:	Lipidem 200 mg/ml Emulsion for Infusion
Greece:	Lipoplus 20%
Italy:	Lipidem 200 mg/ml
Luxembourg:	Lipidem
Netherlands:	Lipoplus 20%
Norway:	Lipidem
Poland:	Lipidem
Portugal:	Lipoplus
Sweden:	Lipoplus
Slovakia:	Lipoplus 20%
Slovenia:	Lipidem 200 mg/ml emulzija za infundiranje

This leaflet was last revised in 03/2016.

The following information is intended for healthcare professionals only:

Method of administration and special precautions for disposal and other handling

Intravenous use.

Lipid emulsions are suitable for peripheral venous administration and can also be administered separately via peripheral veins as part of total parenteral nutrition.

The Y- or the bypass connector should be placed as close to the patient as possible if lipid emulsions are co-administered with amino acid and carbohydrate solutions.

For single use only. Container and unused residues must be discarded after use. Do not reconnect partially used containers. Shake gently prior to use.

Only use containers that are undamaged and in which the emulsion is homogeneous and milky-white. Inspect the emulsion visually for phase separation prior to administration (oil drops, oil layer).

The emulsion has to be brought to room temperature unaided prior to infusion, i.e., the product should not be put in a heating device (such as oven or microwave).

If filters are used, these must be permeable to lipids.

Before infusing a lipid emulsion together with other solutions via a Y connector or bypass set, the compatibility of these fluids should be checked, especially when co-administering carrier solutions to which drugs have been added. Particular caution should be taken when co-infusing solutions that contain divalent cations (such as calcium or magnesium).

Duration of treatment

As clinical experience with long-term use of Lipidem is limited, it should normally not be administered for longer than one week. If parenteral nutrition with lipid emulsions is further indicated, Lipidem can be administered over longer periods provided appropriate monitoring is employed.

Infusion rate

The infusion should be administered at the lowest possible infusion rate. During the first 15 minutes the infusion rate should only be 50% of the maximum infusion rate to be used.

Maximum infusion rate for adults

Up to 0.15 g/kg b.w./h lipids.

Maximum infusion rate for preterm newborn infants, term newborn infants, infants and toddlers

Up to 0.15 g/kg b.w./h lipids.

Maximum infusion rate for children and adolescents

Up to 0.15 g/kg b.w./h lipids.

Interference with laboratory tests

Lipids may interfere with certain laboratory tests (such as bilirubin, lactate dehydrogenase, oxygen saturation) when the blood sample is taken before the lipids have been eliminated from the bloodstream, this may take 4 to 6 hours.

Incompatibilities

Lipidem may only be mixed with other medicinal products for which compatibility has been documented (see section 4.4 of the Summary of Product Characteristics).

Compatibility data for different additives (e.g. carbohydrates, electrolytes, trace elements, vitamins) and the corresponding shelf life of such admixtures can be provided on demand by the manufacturer.

Shelf life after admixture of compatible additives

From a microbiological point of view, the product should be used immediately after admixture of additives. If not used immediately after admixture of additives, in-use storage times and conditions prior to use are the responsibility of the user.

For full information on this product please refer to the Summary of Product Characteristics of Lipidem.

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