Package leaflet: Information for the user

Propofol-Lipuro 2% (20 mg/ml) emulsion for injection or infusion
Propofol

Read all of this leaflet carefully before you start using 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.
- 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 Propofol-Lipuro is and what it is used for

Propofol-Lipuro belongs to a group of medicines called general anaesthetics. General anaesthetics are used to cause unconsciousness (sleep) so that surgical operations or other procedures can be performed. They can also be used to sedate you (so that you are sleepy but not completely asleep).

Propofol Lipuro is used to:
- induce and maintain general anaesthesia in adults and children > 3 years
- sedate patients > 16 years of age receiving artificial respiration in intensive care
- sedate adults and children > 3 years during diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia.

2. What you need to know before you use Propofol- Lipuro

Do not use Propofol-Lipuro:

- if you are allergic to propofol, soya, peanut or any of the other ingredients of this medicine (listed in section 6).

It must not be used in patients of 16 years of age or younger for sedation during intensive care. Safety and efficacy for these age groups have not been demonstrated.

Warnings and precautions

Talk to your doctor or pharmacist before receiving Propofol-Lipuro.

Special care has to be taken
- if you have serious head injuries,
- if you have a mitochondrial disease,
- if you have a disorder in which your body does not handle fat properly,
- if you have any other health problems which require much caution in the use of fat emulsions,
- if your blood volume is too low (hypovolaemia),
- if you have a low protein concentration in your blood (hypoproteinaemia),
- if you are very weak (debilitated) or have heart, kidney or liver problems,
- if you have high pressure within in the skull,

- if you have problems with your breathing,
- if you have epilepsy,
- if you are undergoing some procedures where spontaneous movements are particularly undesirable.

Please tell your doctor if you have one of these diseases or conditions.

If you are receiving other lipids by a drip into your vein at the same time your doctor will pay attention to your total daily fat intake.

Propofol will be administered to you by a physician trained in anaesthesia or intensive care. You will be constantly monitored during anaesthesia and waking-up time.

If you experience signs of the so called 'propofol infusion syndrome' (for a detailed list of the symptoms see section 4 'Possible side effects', 'A doctor must be called immediately if any of the following happens') your doctor will immediately stop the dosage of propofol.

Please see also section 'Driving and using machines' for precautions to be taken after the use of propofol.

Children and adolescents

The use of Propofol-Lipuro is not recommended in children < 3 years of age.

This medicine must not be used in patients of 16 years of age or younger for sedation for intensive care as the safety and efficacy of propofol for sedation in this age group have not been demonstrated (see section 'Do not use Propofol-Lipuro:').

Other medicines and Propofol-Lipuro

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

Propofol has effectively been used with different regional anaesthesia techniques that only numb a part of your body (epidural and spinal anaesthesia).
Additionally, safe use has been demonstrated in combination with

- drugs you receive before surgery
- other medicines like muscle relaxing drugs
- anaesthetic drugs that can be inhaled
- pain killers.

However, your physician may give you lower doses of propofol if general anaesthesia or sedation is needed as a supplement to regional anaesthesia techniques.

Your doctor will consider that other medicines with an inhibiting effect on the central nervous system may increase the effects of propofol when given together with propofol. Special care will also be taken if you receive in parallel an antibiotic containing rifampicin – you may develop profound low blood pressure.

Your dose might be reduced by your doctor if you are also treated with valproate (anticonvulsant).

Propofol-Lipuro with alcohol

Your doctor will advise you on the consumption of alcohol before and after the use of Propofol-Lipuro.

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 or pharmacist for advice before taking this medicine.

Propofol-Lipuro should not be used during pregnancy unless it is definitely needed. It crosses the placenta and may depress the vital functions of the newborn.
However, propofol may be used during an induced abortion.

If you are breast-feeding your child, you should stop nursing and discard breast milk for 24 hours after you have received Propofol-Lipuro. Studies in breast-feeding women showed that propofol is excreted in small amounts into the milk.

Driving and using machines

You should not drive or operate machinery for a while after you have had an injection or infusion of Propofol-Lipuro.

Your doctor will advise you
- if you should be accompanied when you are leaving.
- when you can drive and use machinery again.
- on the use of other tranquillizing drugs (e.g. tranquillizers, strong pain killers, alcohol).

Propofol-Lipuro contains sodium and soya-bean oil

This medicine contains less than 1 mmol sodium (23 mg) per 100 ml, that is to say essentially 'sodium-free'.

Propofol-Lipuro contains soya oil. If you are allergic to peanut or soya, do not use this medicine.

3. How to use Propofol-Lipuro

Propofol-Lipuro will only be given by persons trained in anaesthesia or by specially trained doctors in a hospital or in an adequately equipped day therapy unit.

Dosage

The dose you are given will vary depending on your age, body weight and physical condition. The doctor will give the correct dose to start and to sustain anaesthesia or to achieve the required level of sedation, by carefully watching your responses and vital signs (pulse, blood pressure, breathing, etc).

The doctor will also observe limits of the time of application, if necessary.

Propofol-Lipuro will only be given for a maximum of 7 days.

Method of administration

You will receive Propofol-Lipuro by intravenous injection or infusion, that is, through a needle or small tube placed in one of your veins.

Because Propofol-Lipuro does not contain preservatives, an infusion from one vial of Propofol-Lipuro 2% (20 mg/ml) will not last longer than 12 hours.

Your circulation and breathing will be constantly monitored while you are being given the injection or infusion.

If you received more Propofol-Lipuro than you should

It is unlikely that this occurs because the doses you receive are very carefully controlled.

Yet if you accidentally got an overdose, this could lead to depression of heart function, and breathing. In this case your doctor will employ any necessary treatment immediately.

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

4. Possible side effects

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

A doctor must be called immediately if any of the following happens

Common (may affect up to 1 in 10 people):
- Low blood pressure that might occasionally need infusion of fluids and reduction of the speed of administration of propofol.
- Too low heartbeat that might be serious in rare cases.

Rare (may affect up to 1 in 1,000 people):
- Convulsions like in epilepsy

Very rare (may affect up to 1 in 10,000 people):
- Allergic reactions up to allergic shock including swelling of the face, tongue or throat, wheezing breath, skin redness and low blood pressure
- There have been cases of unconsciousness occurring after operations. You will therefore be carefully observed during the waking-up time.
- Water on the lungs (lung oedema) after administration of propofol
- Inflammation of the pancreas.

Not known (frequency cannot be estimated from the available data):
- There have been reports of isolated cases of severe adverse reactions presenting as a combination of the following symptoms: breakdown of muscle tissue, accumulation of acidic (sour) substances in the blood, abnormally high blood potassium level, high blood fat levels, abnormalities in the electrocardiogram (Brugada-type ECG), liver enlargement, irregular heart-beat, kidney failure and heart failure. This has been called the "*propofol infusion syndrome*". Some of the affected patients eventually died. These effects have only been seen in patients in intensive care, mostly in patients with serious head injuries and in children with respiratory tract infections who received doses higher than 4 mg of propofol per kg body weight per hour. See also section 2, 'Warnings and precautions'.
- Hepatitis (inflammation of the liver), acute liver failure (symptoms can include yellowing skin and eyes, itching, dark coloured urine, stomach pain and liver tenderness (indicated by pain under the front of the rib cage on your right-hand side), sometimes with loss of appetite).

Other side effects are:

Very common (may affect more than 1 in 10 people):
- Pain at the injection site occurring during the first injection. The pain may be reduced by injecting propofol into larger veins of the forearm. Injection of lidocaine (a local anaesthetic) and propofol at the same time also helps to reduce the pain at the injection site.

Common (may affect up to 1 in 10 people):
- Short interruption of breathing
- Headache during the time of recovery
- Sickness or vomiting during the time of recovery

Uncommon (may affect up to 1 in 100 people):
- Blood clots in veins or inflammation of veins at the injection site

Very rare (may affect up to 1 in 10,000 people):
- Loss of sexual control during the time of recovery
- Abnormal colour of urine after longer lasting administration of propofol
- Cases of fever after an operation
- Tissue damage after the medicine was accidentally injected outside of a vein

Not known (frequency cannot be estimated from the available data):
- Involuntary movements
- Abnormally good mood
- Drug abuse and drug dependence
- Failure of the heart
- Cardiac arrest
- Shallow breathing
- Prolonged and painful erection of the penis
- Pain and/or swelling at the injection site after the medicine was accidentally injected outside of a vein
- Breakdown of muscle tissue has been reported very rarely in cases where propofol has been given at greater doses than recommended for sedation in intensive care units

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Propofol-Lipuro

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 carton. The expiry date refers to the last day of that month.

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

Propofol-Lipuro must be used immediately after opening the vial.

Do not use Propofol-Lipuro if two separate layers can be seen after shaking the product or if it is not milky-white.

6. Contents of the pack and other information

What Propofol-Lipuro contains

- The active substance is propofol.
  Each millilitre of Propofol-Lipuro 2% (20 mg/ml) contains 20 mg of propofol.
  1 vial with 50 ml contains 1000 mg propofol.

- The other ingredients are:
  Soya-bean oil refined,
  Medium-chain triglycerides,
  Egg phospholipids for injection,
  Glycerol,
  Sodium oleate,
  Water for injections.

What Propofol-Lipuro looks like and contents of the pack

It is an emulsion for injection or infusion.
It is a milky-white oil-in-water emulsion.

It comes in glass vials of 50 millilitres, available in packs of one or 10 vials.
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

Phone: +49/5661/71-0
Fax: +49/5661/71-4567

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Propofol-Lipuro 2% (20 mg/ml):	Czech Republic, Slovak Republic
Propofol-Lipuro 20 mg/ml:	Estonia, Finland, Germany, Lithuania, Luxembourg, Norway, Sweden
Propofol B. Braun:	Italy
Propofol-Lipuro 2%:	Portugal, Greece
Propofol "B. Braun" 20 mg/ml:	Denmark
Propofol-Lipuro 2% (20 mg/ml):	Poland
Propofol-Lipuro 20 mg/ml, emulsie voor injectie of infusie:	The Netherlands
Propofol-Lipuro 20 mg/ml Emulsion zur Injektion oder Infusion:	Austria
Propofol-Lipuro 20 mg/ml emulzija za injiciranje ali infundiranje:	Slovenia
Propofol-Lipuro 2% (20 mg/ml) emulsion for injection or infusion:	Ireland
PROPOFOL LIPURO 2 % (20 mg/ml), émulsion injectable ou pour perfusion:	France
Propofol 2% (20 mg/ml) emulsion for injection or infusion:	United Kingdom (Northern Ireland)
PROPOFOL LIPURO 20 mg/ml emulsión inyectable y para perfusión:	Spain

This leaflet was last revised in 07/2024.

The following information is intended for healthcare professionals only:
The containers are for single use in one patient only.
The containers must be shaken before use.
Before use, the surface of the rubber stopper of the vial should be cleaned with medicinal alcohol (spray or swabs). After use, tapped containers must be discarded.

The infusion line and the reservoir of Propofol-Lipuro must be discarded and replaced after 12 hours at the latest.

Any unused emulsion must be thrown away at the end of administration. Any unused product or waste material should be disposed of in accordance with local requirements.

For complete information on this medicinal product please refer to the summary of product characteristics.