Package leaflet: Information for the user

Propofol 1% (10 mg/ml) emulsion for injection/infusion

Propofol

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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Propofol 1% is and what it is used for

Propofol 1% 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 1% emulsion for injection or infusion is used to:
- induce and maintain general anaesthesia in adults, adolescents and children older than 1 month.
- sedate patients older than 16 years of age receiving artificial respiration in intensive care.
- sedate adults, adolescents and children older than 1 month during diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia.

2. What you need to know before you are given Propofol 1%

Do not use Propofol 1%

- if you are allergic to propofol, soya, peanut or any of the other ingredients of this medicine (listed in section 6).
- in patients of 16 years of age or younger for sedation in intensive care.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Propofol 1% and if any of the subsequent mentioned applies to you or applied to you in the past.

You should not receive Propofol 1% or only under extreme caution and intensive monitoring, if you:
- have advanced heart failure
- have any other serious disease of the heart
- are receiving electroconvulsive therapy (ECT, a treatment for psychiatric problems)

In general, Propofol 1% should be given with caution to elderly or weak patients.

Before receiving Propofol 1% , tell your anaesthetist or intensive care doctor if you have:
- heart disease
- lung disease
- kidney disease
- liver disease
- seizures (epilepsy)
- a raised pressure inside the skull (raised intracranial pressure). In combination with low blood pressure the amount of blood reaching the brain may be decreased.
- altered levels of fat in the blood. If you are receiving total parenteral nutrition (feeding through a vein), the levels of fat in your blood must be monitored.
- if your body has lost lots of water (you are hypovolaemic).

If you have any of the following conditions, they must be treated before you receive Propofol 1% :

- heart failure
- when there is insufficient blood reaching the tissues (circulatory failure)
- severe breathing problems (respiratory failure)
- dehydration (hypovolaemia)
- seizures (epilepsy)

Propofol 1% may increase the risk of
- epileptic seizures
- a nervous reflex that slows the heart rate (vagotonia, bradycardia)
- changes in the blood flow to the organs of the body (haemodynamic effects on the cardiovascular system) if you are overweight and receive high doses of Propofol 1% .

Involuntary movements can occur during sedation with Propofol 1% . The doctors will take into account how this might affect surgical procedures being performed under sedation and will take the necessary precautions.

Very occasionally, after anaesthesia, there may be a period of unconsciousness associated with stiffness of the muscles. This requires observation by the medical staff but no other treatment. It will resolve spontaneously.

The injection of Propofol 1% can be painful. A local anaesthetic can be used to reduce this pain but can have its own side effects.

You will not be allowed to leave the hospital until you are fully awake.
If you are able to go home shortly after receiving propofol you should not go home unaccompanied.

Children and adolescents
The use of Propofol 1% emulsion for injection or infusion is not recommended for use in new-born infants or children younger than 1 month.
Due to the limited data available, the use of target controlled infusion (TCI) in the paediatric population below 2 years of age cannot be recommended.
Propofol 1% must not be given to children and adolescents younger than 16 years of age for sedation in the intensive care unit, since its safety has not been demonstrated in this patient group for this indication.

Other medicines and Propofol 1%
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor, anaesthetist or nurse if you are taking any of the following medicines:
- Rifampicin (for tuberculosis – TB).
- Midazolam (used to induce sedation (a very relaxed state of calm, drowsiness or sleep) and relieves anxiety and muscle tension).

You must take special care if you are also taking/receiving any of the following medicines:
- Premedications (your anaesthetist will know which medicines can be influenced by Propofol 1%).
- Other anaesthetics, including general, regional, local and inhalational anaesthetics (Lower doses of Propofol 1% may be required. Your anaesthetist will know this.)
- Painkillers (analgesics)
- Strong painkillers (fentanyl or opioids)
- Parasympatholytic agents (medicines used to treat e.g. painful cramps of organs, asthma or Parkinson's disease)
- Benzodiazepines (medicines used to treat anxiety)
- Suxamethonium (muscle relaxant)
- Drugs that affect many of the internal body functions such as the heart rate, e.g. atropine
- Alcohol containing medicines or beverages
- Neostigmine (medicine used to treat a disease called myasthenia gravis)
- Cyclosporine (medicine used to prevent transplant rejections)
- Valproate (medicine used to treat epilepsy or mental disorders)

Propofol 1% with food, drink and alcohol
After you have been given Propofol 1% , you should not eat, drink or consume alcohol until fully recovered.

Pregnancy and breastfeeding
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 1% should not be given to pregnant women unless clearly necessary.
You should stop breast-feeding and discard any breast milk for 24 hours after receiving Propofol 1% .

Driving and using machines
After having propofol you may still feel sleepy for some time.
Do not drive or use any tools or machines until you are sure the effects have worn off.
If you are able to go home shortly after receiving Propofol, do not drive a car or go home unaccompanied.
Ask your doctor when you can start doing these activities again and when you can go back to work.

Propofol 1% contains soya-bean oil and sodium
Propofol 1% contains soya-bean oil. If you are allergic to peanut or soya, do not use this medicinal product.

This medicinal product contains less than 1 mmol (23 mg) sodium per 100 ml, i.e. essentially ´sodium-free`.

3. How to use Propofol 1%

Propofol 1% will only be given to you in hospitals or suitable therapy units by or under the direct supervision of your anaesthetist or intensive care doctor.
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).

You may need several different medicines to keep you asleep or sleepy, free from pain, breathing in a healthy way and to keep your blood pressure steady. The doctor will decide which medicines you need and when you need them.

Adults
Most people need 1.5 - 2.5 mg propofol per kg body weight to make them go to sleep (induction of anaesthesia), and then 4 to 12 mg propofol per kg body weight per hour after this to keep them asleep (maintenance of anaesthesia). For sedation, doses of 0.3 to 4.0 mg propofol per kg body weight per hour are usually sufficient.

For sedation during surgical and diagnostic procedures in adults, most patients will require 0.5 - 1 mg propofol per kg body weight over 1 to 5 minutes for onset of sedation. Maintenance of sedation may be accomplished by titrating Propofol 1% infusion to the desired level of sedation. Most patients will require 1.5 - 4.5 mg propofol per kg body weight per hour. The infusion may be supplemented by bolus administration of 10 - 20 mg propofol (1 - 2 ml Propofol 1% emulsion for injection or infusion) if a rapid increase of the depth of sedation is required.

To provide sedation for ventilated patients older than 16 years of age under intensive care conditions the dose will be adjusted according to the depth of sedation required. Usually satisfactory sedation is achieved by continuous infusion with administration rates in the range of 0.3 to 4.0 mg propofol per kg body weight per hour. Rates of infusion greater than 4.0 mg propofol per kg bodyweight per hour are not recommended.

Elderly and weak patients
Elderly and weak patients may require lower doses.

Use in children and adolescents over one month of age
The use of Propofol 1% is not recommended in children younger than 1 month.
Special care should also be observed when administering Propofol 1% emulsion for injection or infusion to children less than 3 years of age. However, evidence now available does not suggest that this is any less safe than in children older than 3 years.
The dose should be adjusted according to age and/or body weight. Most patients over 8 years of age require approximately 2.5 mg/kg bodyweight Propofol 1% to make them go to sleep (induction of anaesthesia). In younger children, especially between the age of 1 month and 3 years, dose requirements may be higher (2.5 - 4 mg/kg bodyweight).
Rates in the region of 9 - 15 mg/kg/h usually achieve satisfactory anaesthesia to keep them asleep (maintenance of anaesthesia). In younger children, especially between the age of 1 month and 3 years, dose requirements may be higher.

For sedation during surgical and diagnostic procedures in children over 1 month of age with Propofol 1% emulsion for injection or infusion most paediatric patients require 1 - 2 mg/kg bodyweight propofol for onset of sedation. Maintenance of sedation may be accomplished by titrating Propofol 1% infusion to the desired level of sedation. Most patients require 1.5 - 9 mg/kg/h propofol. The infusion may be supplemented by bolus administration of up to 1 mg/kg bodyweight if a rapid increase of depth of sedation is required.

Propofol 1% emulsion for injection or infusion must not be given to children and adolescents younger than 16 years of age for sedation in the intensive care unit, since its safety has not been demonstrated in this patient group for this indication.

Method of administration
Propofol 1% is for intravenous use, usually administered on the back of your hand or in the forearm. Your anaesthetist may use a needle or cannula (a fine plastic tube). Propofol 1% will be injected into a vein either manually or by electric pumps.

Propofol 1% is for single use only. Any unused emulsion must be discarded. Containers should be shaken before use If two layers can be seen after shaking the emulsion should not be used. Use only homogeneous preparations and undamaged containers.

Prior to use, the rubber membrane should be cleaned using an alcohol spray or a swab dipped in alcohol.

Duration of treatment
When used for sedation, Propofol 1% must not be administered for more than 7 days.

If you received more propofol than you should
Your doctor will ensure that you receive the right amount of propofol for you and for the procedure you are undergoing.
However, different people need different doses and if you do receive too much for you, your anaesthetist may need to take measures to make sure your heart and breathing are adequately supported. This is why anaesthetic drugs are only administered by doctors trained in anaesthesia or in the care of patients in intensive care.

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

4. Possible side effects

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

Side effects that can happen during anaesthesia
The following side effects can happen during anaesthesia (while the injection is being given to you or when you are sleepy or asleep). Your doctor will be looking out for these. If they happen, your doctor will give you appropriate treatment.

Very common (may affect more than 1 in 10 people)
- A feeling of pain at the site of the injection (while the injection is being given, before you fall asleep).

Common (may affect up to 1 in 10 people)
- Slow or fast heartbeat
- Low blood pressure
- Changes in your breathing pattern (low respiratory rate, breathing arrest)
- Hiccups
- Cough (may also happen when you wake up)

Uncommon (may affect up to 1 in 100 people)
- Swelling and redness or blood clots at the vein along the injection site.

Rare (may affect up to 1 in 1,000 people)
- Twitching and shaking of your body, or fits (may also happen when you wake up).

Very rare (may affect up to 1 in 10, 000 people)
- Serious allergic reaction which causes difficulty in breathing, swollen and reddened skin, hot flushes
- Build up of fluid in the lungs which can make you very breathless (may also happen when you wake up)
- Unusual colour of urine (may also happen when you wake up).

Not known (frequency cannot be estimated from the available data)
- Involuntary movements
- Severe skin and tissue reaction following accidental application beside the vein.
- Prolonged, often painful erection (priapism).

Side effects that can happen after anaesthesia
The following side effects can happen after anaesthesia (when you are waking up or after you have woken up).

Common (may affect up to 1 in 10 people)
- Headache
- Feeling sick (nausea), being sick (vomiting).
- Cough.

Rare (may affect up to 1 in 1,000 people)
- Dizziness, chills and sensations of cold
- Excitations

Very rare (may affect up to 1 in 10,000 people)
- Being unconscious after the operation (when this has happened, the patients have recovered without problems)
- Inflamed pancreas (pancreatitis) which causes severe stomach pain (a causal relationship could not be shown)
- Fever following surgery

Not known (frequency cannot be estimated from the available data)
- Feeling euphoric
- Feeling sexually aroused
- Irregular heart beat
- Changes in ECG (Brugada type ECG)
- Increase in liver size
- Kidney failure
- Breakdown of muscle cells (rhabdomyolysis), increase in acidity of your blood, high potassium and fat levels in your blood, heart failure
- Drug abuse, mostly by healthcare professionals
- Prolonged, often painful erection (priapism).

When Propofol 1% is administered in combination with lidocaine (a local anaesthetic used to reduce the pain at the site of injection), certain side effects may occur rarely:
- dizziness
- vomiting
- sleepiness
- fits
- a slowing of the heart rate (bradycardia)
- irregular heartbeat (cardiac arrhythmias)
- shock

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

For the UK: Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

For Ireland: HPRA Pharmacovigilance. Website:www.hpra.ie.

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

5. How to store Propofol 1%

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 ampoule/vial and the outer packaging after EXP. The expiry date refers to the last day of that month.

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

After first opening the medicinal product must be used immediately.
Administration systems with undiluted Propofol 1% should be replaced 12 hours after opening of the ampoule or vial.
Dilutions with glucose 50 mg/ml (5 %) solution for injection or sodium chloride 9 mg/ml (0.9 %) solution for injection or an admixture with preservative-free lidocaine 10 mg/ml (1 %) solution for injection (at least 2 mg propofol per ml) should be prepared aseptically (controlled and validated conditions preserved) immediately before administration and has to be administered within 6 hours after preparation.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Propofol 1% contains

- The active substance is propofol.

Each ml emulsion contains 10 mg propofol.
Each 20 ml ampoule contains 200 mg propofol.
Each 20 ml vial contains 200 mg propofol.
Each 50 ml vial contains 500 mg propofol.
Each 100 ml vial contains 1000 mg propofol.

- The other ingredients are soya-bean oil, refined, medium-chain triglycerides, purified egg phosphatides, glycerol, oleic acid, sodium hydroxide, water for injections.

What Propofol 1% looks like and contents of the pack

Propofol 1% is a white oil-in-water emulsion for injection or infusion.

Propofol 1% is available in colourless glass ampoules or glass vials. The glass vials are sealed with rubber stoppers.

Pack sizes:
Packs containing 5 glass ampoules with 20 ml emulsion
Packs containing 10 glass ampoules with 20 ml emulsion
Packs containing 1 glass vial with 20, 50 or 100 ml emulsion
Packs containing 5 glass vials with 20 ml emulsion
Packs containing 10 glass vials with 20, 50 or 100 ml emulsion
Packs containing 15 glass vials with 50 or 100 ml emulsion
Not all pack sizes may be marketed.

Marketing Authorisation Holder

For UK
Fresenius Kabi Limited
Cestrian Court,
Eastgate Way,
Manor Park,
Runcorn,
Cheshire,
WA7 1NT

UK

For IE
Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1,
Bad Homburg v.d.H. 61352,
Germany

Manufacturer:
Fresenius Kabi Austria GmbH
A-8055 Graz, Hafnerstraße 36
Austria

Fresenius Kabi AB
S-75174 Uppsala, Rapsgatan 7
Sweden

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

Name of the member state	Name of the medicinal product
Austria	Propofol “Fresenius” 1 % mit MCT - Emulsion zur Injektion oder Infusion
Belgium	Propolipid 1 %
Bulgaria	Пропофол MCT/LCT Фрезениус 10 mg/ml инжекционна/инфузионна емулсия
Cyprus	Propofol 1% MCT/LCT Fresenius
Czech Republic	Propofol MCT/LCT Fresenius 10 mg/ml injekční/infuzní emulze
Denmark	Propolipid
Estonia	Propoven 1%
Germany	Propofol 1% (10 mg/1 ml) MCT Fresenius, Emulsion zur Injektion oder Infusion
Greece	Propofol MCT/LCT 1%
Finland	Propolipid 10 mg/ml
Hungary	Propofol 1% MCT/LCT Fresenius
Iceland	Propolipid 10 mg/ml
Ireland	Propofol 1% (10 mg/ml) emulsion for injection/infusion
Italy	Propofol Kabi
Latvia	Propoven 1%
Lithuania	Propoven 1%
Luxembourg	Propofol 1% MCT Fresenius
Netherlands	Propofol 10 mg/ml MCT/LCT Fresenius
Norway	Propolipid 10 mg/ml
Poland	Propofol 1% MCT/LCT Fresenius
Portugal	Propofol 1% MCT/LCT Fresenius
Romania	Propofol MCT/LCT Fresenius 10 mg/ml emulsie injectabilă/perfuzabilă
Slovakia	Propofol MCT/LCT Fresenius 10 mg/ml injekčná/infúzna emulzia
Slovenia	Propoven 10 mg/ml emulzija za injiciranje ali infundiranje
Spain	Propofol Lipoven Fresenius 10 mg/ml emulsión inyectable y para perfusión
Sweden	Propolipid 10 mg/ml
United Kingdom	Propofol 1% (10 mg/ml) emulsion for injection/infusion

This leaflet was last revised in January 2024.

The following information is intended for healthcare professionals only:

Propofol 1% emulsion for injection or infusion should not be mixed prior to administration with injection or infusion solutions other than glucose 50 mg/ml (5 %) solution for injection or sodium chloride 9 mg/ml (0.9 %) solution for injection or preservative free lidocaine 10 mg/ml (1 %) solution for injection. Final propofol concentration must not be below 2 mg/ml.

For single use only. Any unused emulsion must be discarded.

Containers should be shaken before use.
If two layers can be seen after shaking the emulsion should not be used.
Use only homogeneous preparations and undamaged containers.

Prior to use, the ampoule neck or rubber membrane should be cleaned using an alcohol spray or a swab dipped in alcohol. After use, tapped containers must be discarded.

Propofol should be given by those trained in anaesthesia (or, where appropriate, doctors trained in the care of patients in Intensive Care).
Patients should be constantly monitored and facilities for maintenance of a patent airway, artificial ventilation, oxygen enrichment and other resuscitative facilities should be readily available at all times.
Propofol should not be administered by the person conducting the diagnostic or surgical procedure.

Abuse of, and dependence on propofol, predominantly by health care professionals, have been reported.
As with other general anaesthetics, the administration of propofol without airway care may result in fatal respiratory complications.

When propofol is administered for conscious sedation, for surgical and diagnostic procedures, patients should be continually monitored for early signs of hypotension, airway obstruction and oxygen desaturation.

Propofol 1% emulsion for injection or infusion may be administered undiluted or diluted in glucose 50 mg/ml (5 %) solution for injection or sodium chloride 9 mg/ml (0.9 %) solution for injection.
Propofol 1% emulsion for injection or infusion must not be mixed with any other solutions for infusion or injection except those mentioned above.
Glucose 50 mg/ml (5 %) solution for injection, sodium chloride 9 mg/ml (0.9 %) solution for injection or sodium chloride 1.8 mg/ml (0.18 %) solution for injection and glucose 40 mg/ml (4 %) solution for injection may be given through the same infusion set.
Co-administration of other medicinal products or fluids added to the Propofol 1% infusion line must occur close to the cannula site using a Y-piece connector or a three-way valve.

Propofol 1% is a lipid containing emulsion without antimicrobial preservatives and may support rapid growth of microorganisms.

The emulsion must be drawn aseptically into a sterile syringe and giving set immediately after opening the ampoule or breaking the vial seal. Administration must commence without delay.

Asepsis must be maintained for both Propofol 1% and the infusion equipment throughout the infusion period. Propofol 1% must not be administered through a microbiological filter.

<u>Infusion of undiluted Propofol 1%:</u>
The use of a burette, drop counter, syringe pump or volumetric infusion pump to control the infusion rate is recommended when Propofol 1% is infused undiluted.

As usual for fat emulsions, the infusion of Propofol 1% via one infusion system must not exceed 12 hours. The infusion set for Propofol 1% must be changed at least every 12 hours.

<u>Infusion of diluted Propofol 1%:</u>
Burettes, drop counters or volumetric infusion pumps should always be used to control infusion rates. The maximum dilution must not exceed 1 part of Propofol 1% emulsion for injection or infusion with 4 parts of glucose 50 mg/ml (5 %) solution for injection or sodium chloride 9 mg/ml (0.9%) solution for injection (minimum concentration 2 mg propofol per ml). The mixture should be prepared aseptically (controlled and validated conditions preserved) immediately prior to administration and must be administered within 6 hours after preparation.

To reduce pain on the injection site, Propofol 1% should be administered in a larger vein and/or lidocaine injection solution may be administered before induction of anaesthesia with Propofol 1% . Alternatively, lidocaine may be added to the solution (20 parts of Propofol 1% emulsion for injection or infusion with up to 1 part of 1 % preservative free lidocaine solution for injection) to reduce pain at the site of injection of Propofol 1% emulsion for injection or infusion . Intravenous lidocaine must not be used in patients with hereditary acute porphyria.

Muscle relaxants like atracurium and mivacurium should only be administered after flush of the same infusion site used for Propofol 1% .