Read all of this leaflet carefully before you start using this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Propofol Fresenius is and what it is used for
2. Before you use Propofol Fresenius
3. How to use Propofol Fresenius
4. Possible side effects
5. How to store Propofol Fresenius
6. Further information

1. WHAT PROPOFOL FRESENIUS IS AND WHAT IT IS USED FOR

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

2. BEFORE YOU USE PROPOFOL FRESENIUS

DO NOT use Propofol Fresenius

- if you are hypersensitive (allergic) to propofol or to any of the other ingredients of this medicine (see section 6 “Further information” at the end of this leaflet).

- if you are hypersensitive (allergic) to soya or peanut (see “Important information about some of the ingredients of Propofol Fresenius” at the end of section 2).

- in patients of 16 years of age or younger for sedation in intensive care.

Take special care with Propofol Fresenius
You should not receive Propofol Fresenius, 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)

The use of Propofol Fresenius is not recommended in newborn infants. Special care should also be observed when administering Propofol Fresenius to children less than 3 years of age. However, evidence now available does not suggest that this is any less safe than in older children. The safety of propofol for sedation in children and adolescents 16 years of age and younger in the intensive care unit has not been demonstrated.

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

Before receiving Propofol Fresenius, 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 receiving total parenteral nutrition (feeding through a vein), the levels of fat in your blood must be monitored.

If you have any of the following conditions, they must be treated before you receive Propofol Fresenius:
- heart failure
- when there is insufficient blood reaching the tissues (circulatory failure)
- severe breathing problems (respiratory failure)
- dehydration (hypovolaemia)
- seizures (epilepsy)

Propofol Fresenius 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 Fresenius.

Involuntary movements can occur during sedation with Propofol Fresenius. 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 Fresenius 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.

**Using other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You must take special care if you are also taking any of the following medicines:
- premedications (your anaesthetist will know which medicines may interact with Propofol Fresenius)
- other anaesthetics, including general, regional, local and inhalational anaesthetics (Lower doses of Propofol Fresenius may be required. Your anaesthetist will know this.)
- analgesics (painkillers)
- drugs that relax muscles, e.g. suxamethonium
- benzodiazepines (drugs for anxiety)
- drugs that affect many of the internal body functions such as the heart rate, e.g. atropine
- strong painkillers, e.g. fentanyl
- alcohol
- neostigmine (a treatment for muscle weakness)
- cyclosporin (used to prevent transplant rejections)

**Using Propofol Fresenius with food and drink**
After you have been given Propofol Fresenius, you should not drink alcohol until fully recovered.

**Pregnancy and breast-feeding**
Ask your doctor or pharmacist for advice before taking any medicine.
Propofol Fresenius should not be given to pregnant women unless necessary. Mothers should stop breast-feeding and discard any breast milk for 24 hours after receiving Propofol Fresenius.

**Driving and using machines**
After you have been given Propofol Fresenius, you must not drive, operate machinery, or work in dangerous situations. You should not go home alone.

**Important information about some of the ingredients of Propofol Fresenius**
Propofol Fresenius contains soya-bean oil. This can rarely cause severe hypersensitivity (allergic) reactions (see “Do not use Propofol Fresenius”). Tell your doctor if you know that you have allergic reactions to soya-bean oil.

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

**3. HOW TO USE PROPOFOL FRESENIUS**
Propofol Fresenius will only be given to you in hospitals or suitable therapy units by your anaesthetist or by an intensive care doctor.
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). It can also be affected by other medicines you may be taking. 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 Fresenius 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% (10 mg/1 ml) Fresenius) if a rapid increase of the depth of sedation is required.

Propofol Fresenius is for intravenous use, usually on the back of your hand or in the forearm. Your anaesthetist may use a needle or cannula (a fine plastic tube). An electric pump may be used to give the injection for long operations and for use in intensive care.

Elderly and weak patients may require lower doses.

Children usually require slightly higher doses. The dose should be adjusted according to age and/or body weight.

When used for sedation, Propofol Fresenius must not be administered for more than 7 days.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Propofol Fresenius can cause side effects, although not everybody gets them.

Evaluation of the side effects is based on the following frequencies:

<table>
<thead>
<tr>
<th>Very common</th>
<th>affects more than 1 user in 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common</td>
<td>affects 1 to 10 users in 100</td>
</tr>
<tr>
<td>Uncommon</td>
<td>affects 1 to 10 users in 1,000</td>
</tr>
<tr>
<td>Rare</td>
<td>affects 1 to 10 users in 10,000</td>
</tr>
<tr>
<td>Very rare</td>
<td>affects less than 1 user in 10,000</td>
</tr>
<tr>
<td>Not known</td>
<td>frequency cannot be estimated from the available data</td>
</tr>
</tbody>
</table>

If you think you have any of the below mentioned side effects or any other side effects, please inform a physician as soon as possible.

**Very common:**
- local pain during the injection
**Common:**
- increase of levels of fat in the blood (hypertriglyceridemia)

These side effects may occur during the induction of anaesthesia:
- spontaneous movements
- muscle jerks (myoclonus)
- muscle twitching (minimal excitation)
- low blood pressure (hypotension)
- slow heartbeat (bradycardia)
- rapid heartbeat (tachycardia)
- hot flushes
- increased breathing (hyperventilation)
- stopping breathing (temporary apnoea)
- coughing after anaesthesia
- hiccups (singultus)

**Uncommon:**
- severe low blood pressure (hypotension)
- coughing during anaesthesia
- slowing of the pulse rate (progressive bradycardia)

**Rare:**
- a severe allergic reaction (anaphylaxis), including:
  - swelling of the skin of the face, mouth and throat (angioedema)
  - narrowing of the airways in the lungs that makes it difficult to breathe (bronchospasm)
  - reddening of the skin (erythema)
  - low blood pressure (hypotension)
- headache
- dizziness (vertigo)
- epileptiform movements (involuntary movements similar to epilepsy), including convulsions and opisthotonus (a rigid posture with the head arched backwards)
- blood clots (thrombosis)
- inflammation of the blood vessels (phlebitis)
- discoloration of urine
- postoperative fever

These rare side effects may occur during the recovery period (waking up):
- euphoria (feeling happy) and sexual arousal
- shivering and feeling cold
- irregular heartbeat (arrhythmia)
- coughing
- feeling sick (nausea) or vomiting
Very rare:
- allergic reactions caused by soya-bean oil
- delayed epileptiform attacks (involuntary movements similar to epilepsy after waking up)
- convulsions in epileptic patients
- unconsciousness after anaesthesia
- fluid on the lungs (pulmonary oedema)
- inflammation of the pancreas (pancreatitis)
- severe tissue responses after accidental injection into tissues
- rhabdomyolysis (a disorder of muscle)
- a change in the acidity of the blood (metabolic acidosis)
- a high level of potassium in the blood (hyperkalaemia)
- heart failure.

When Propofol Fresenius 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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PROPOFOL FRESENIUS

Keep out of the reach and sight of children.

Do not use Propofol Fresenius 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 opening the product must be used immediately.
Administration systems with undiluted Propofol Fresenius should be replaced 12 hours after opening of the ampoule or vial. Dilutions with 5% w/v glucose or 0.9% w/v sodium chloride intravenous infusion solution or an admixture with 1% preservative-free lidocaine injection solution (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.

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

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Propofol 1% (10 mg/1 ml) Fresenius contains

- The active substance is propofol.

1 ml emulsion contains 10 mg propofol.
Each 20 ml ampoule 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, purified egg phosphatides, glycerol, oleic acid, sodium hydroxide, water for injections.

What Propofol Fresenius looks like and contents of the pack

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

Propofol Fresenius 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 1 glass vial with 50 or 100 ml emulsion
Packs containing 10 glass vials with 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 and Manufacturer

Marketing Authorisation Holder:

Fresenius Kabi Deutschland GmbH
61346 Bad Homburg v.d.H
Bad Homburg
Germany
Manufacturer:
Fresenerstrasse Kabi Austria GmbH
A 8055 Graz, Hafnerstrasse 36
Austria

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

<table>
<thead>
<tr>
<th>Country</th>
<th>Trade Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium</td>
<td>Propofol Fresenius 1 %</td>
</tr>
<tr>
<td>Denmark</td>
<td>Propofol Fresenius Kabi</td>
</tr>
<tr>
<td>Germany</td>
<td>Propofol 1% (10mg/1 ml) Fresenius, Emulsion zur Injektion oder Infusion</td>
</tr>
<tr>
<td>Greece</td>
<td>Propofol 1 % Fresenius</td>
</tr>
<tr>
<td>Finland</td>
<td>Propofol Fresenius Kabi 10 mg/ml</td>
</tr>
<tr>
<td>France</td>
<td>Propofol Fresenius 10 mg/ml, emulsion injectable ou pour perfusion</td>
</tr>
<tr>
<td>Ireland</td>
<td>Fresenius Propofol 1%</td>
</tr>
<tr>
<td>Portugal</td>
<td>Propofol 1 % Fresenius</td>
</tr>
<tr>
<td>Spain</td>
<td>Propofol Fresenius 10 mg/ml emulsión para inyección o perfusión</td>
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<tr>
<td>Sweden</td>
<td>Propofol Fresenius Kabi 10 mg/ml</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Fresenius Propofol 1 %</td>
</tr>
</tbody>
</table>

This leaflet was last approved in ... December 2012

To report any side effects:

- Saudi Arabia:
  - National Pharmacovigilance Center (NPS)
    - Fax: + 966-1-210-7398
    - E-mail: npc.drug@sfd.gov.sa/nps

- Other GCC states:
  - Please contact the relevant competent authority

Council of Arab Health Ministers
The following statements issued by the council of Arab Health Ministers should be printed in PIL.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed to you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

The following information is intended for medical or healthcare professionals only:

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

For single use. 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 Fresenius must only be given in hospitals or adequately equipped day therapy units by physicians trained in anaesthesia or in the care of patients in intensive care.
For sedation during surgical and diagnostic procedures Propofol Fresenius should not be administered by the same person conducting the surgical or diagnostic procedure.

Circulatory and respiratory functions should be constantly monitored (e.g. ECG, pulse oxymetry) and facilities for maintenance of patient airways, artificial ventilation, and other resuscitation facilities should be immediately available at all times.

Propofol 1% (10 mg/1 ml) Fresenius may be administered undiluted or diluted in 5% w/v glucose or 0.9% w/v sodium chloride intravenous infusion solutions.
5% w/v Glucose intravenous infusion solution, 0.9% w/v sodium chloride intravenous infusion solution or 0.18% w/v sodium chloride and 4% w/v glucose intravenous infusion solution may be given through the same infusion set. Propofol 1% (10 mg/1 ml) Fresenius must not be mixed with any other solutions for infusion or injection.
Co-administration of other medicinal products or fluids added to the Propofol Fresenius infusion line must occur close to the cannula site using a Y-piece connector or a three-way valve.

Propofol Fresenius 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 or giving set immediately after opening the ampoule or breaking the vial seal. Administration must commence without delay.

Asepsis must be maintained for both Propofol Fresenius and the infusion equipment throughout the infusion period. Propofol Fresenius must not be administered through a microbiological filter.
Infusion of undiluted Propofol 1% (10 mg/1 ml) Fresenius:
The use of a burette, drop counter, syringe pump or volumetric infusion pump to control the infusion rate is recommended when Propofol Fresenius is infused undiluted.

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

Infusion of diluted Propofol 1% (10 mg/1 ml) Fresenius:
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% (10 mg/1 ml) Fresenius to 4 parts of 5% w/v glucose or 0.9% w/v sodium chloride intravenous infusion solution (minimum concentration 2 mg propofol per ml). The mixture should be prepared aseptically and administered within 6 hours.

If the same injection system used for the Propofol 1% (10 mg/1 ml) Fresenius is to be used for the injection of muscle relaxants (e.g. atracurium and mivacurium), the injection system must first be flushed.

Lidocaine may be added to the solution (20 parts of Propofol 1% (10 mg/1 ml) Fresenius to 1 part of 1% preservative free lidocaine solution for injection) to reduce pain at the site of injection of Propofol 1% (10 mg/1 ml) Fresenius. 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 Fresenius.