Read all of this leaflet carefully before you are given this medicine.

If you have any questions, ask your doctor or pharmacist.

Possible side effects are listed in this leaflet, please tell your doctor or pharmacist if you notice any side effects not included in this leaflet.

Propofol is a sedative/hypnotic used to:

• induce and maintain general anaesthesia in adults, adolescents 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 anaesthetic

1. What Propofol is and what it is used for

2. Before you are given Propofol

3. How you are given Propofol

4. Possible side effects

5. How to store Propofol

6. Further information.

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The neuromuscular blocking agents, atracurium and mivacurium should not be given through the same intravenous line within 12 hours after preparation.

- When Propofol is administered in combination with lidocaine (a local anesthetic used to reduce the pain at the site of injection), certain side effects may occur rarely:
  - dizziness
  - weakness
  - tachypnea
  - irregular heartbeat (cardiac arrhythmia)

- Keep out of reach of children.

- Only use Propofol after the expiry date which is stated on the vial and the outer carton after “Exp.”. The expiry date refers to the last day of that month.

- Store below 30°C. Do not freeze.

- After opening the product must be used immediately.

- Dilute with glucose 50 mg/ml (5%) solution for injection, sodium chloride 9 mg/ml (0.9%) solution for injection or sodium chloride 0.18% (0.9%) solution for injection and preservative-free lidocaine 10 mg/ml (1%) solution for injection. For single use. Any unused emulsion must be discarded.

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

  - Austria: Sefol (Propofol 10mg/ml Emulsion zur Injektion/Infusion)
  - Belgium: Profast 10mg/ml Emulsion for Injection/Infusion
  - Bulgaria: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Croatia: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Czech Republic: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Denmark: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Estonia: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Finland: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - France: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Germany: Propofol Norameda
  - Greece: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Hungary: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Ireland: Propofol 10mg/ml Emulsion for Injection/Infusion
  - Italy: Propofol 10mg/ml Emulsion for Injection/Infusion
  - Latvia: Rapiva 10 mg/ml emulsion for injection/infusion (Rapiva 10 mg/ml emulsija injekcijām/infūzijām)
  - Lithuania: Spiva (Propofol 10 mg/ml injekcinę/infuzinę emulsija)
  - Luxembourg: Spiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Netherlands: Rapiva (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Norway: Spifol (Propofol, 10mg/ml Emulsion for Injection/Infusion)
  - Poland: Propofol Norameda
  - Portugal: Propofol 10mg/ml Emulsion for Injection/Infusion
  - Romania: Profast 10mg/ml emulsie injectabila/perfuzabila
  - Slovakia: Profast 10mg/ml Emulsion for Injection/Infusion
  - Slovenia: Rapiva 10mg/ml emulzija za injiciranje/infundiranje
  - Spain: Propofol 10 mg/ml Emulsión Inyectable
  - Sweden: Propofol 10 mg/ml Emulsion for Injection/Infusion
  - Switzerland: Propofol 10 mg/ml Emulsion for Injection/Infusion
  - United Kingdom: Propofol 10mg/ml Emulsion for Injection/Infusion

- In cases where the use of preservatives is not possible, all further dilution must be carried out with propofol diluent of 4% dextrose solution without preservatives (minimum concentration 2 mg propofol/ml). The mixture should be prepared aseptically (controlled and validated conditions preserved) immediately prior to administration and must be administered within 12 hours after preparation.

- Containers should be shaken before use. The emulsion should be used immediately after shaking.

- This emulsion must be drawn aseptically into a sterile syringe or administration set immediately after breaking the vial seal. Administration must commence without delay.

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

- Propofol must only be given in hospitals or adequately equipped clinics by physicians trained in anesthesia or the care of patients in intensive care.

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

- For sedation during surgical and diagnostic procedures Propofol should not be administered by the same person conducting the surgical or diagnostic procedure.

- When Propofol is infused, it is recommended that equipment such as burettes, drop counter, syringe pump or volumetric infusion pumps should always be used to control infusion rates.

- Containers should be shaken before use. The emulsion must be prepared close to the cannula site using a Y-piece connector or a three-way valve.

- If two layers can be seen after shaking the emulsion should not be used.

- Use only homogeneous preparations and undamaged containers.

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

- Your anaesthetist and hospital pharmacists are responsible for the correct storage, use and disposal of Propofol.