

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **Propofol 10 mg/ml, emulsion for injection or infusion**

#### Propofol

#### **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.
- 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.

#### **In this leaflet:**

1. What Propofol 10 mg/ml is and what it is used for
2. Before you use Propofol 10 mg/ml
3. How to use Propofol 10 mg/ml
4. Possible side effects
5. How to store Propofol 10 mg/ml
6. Further information

### **1. WHAT IS PROPOFOL 10 MG/ML AND WHAT IT IS USED FOR**

#### **Medicinal product group**

Propofol 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).

#### **What is Propofol used for?**

- To induce and maintain general anaesthesia in adults and children more than 1 month
- To sedate patients more than 16 years of age receiving artificial respiration in intensive care
- To sedate adults and children more than 1 month during diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia

### **2. BEFORE YOU USE PROPOFOL 10 MG/ML**

#### **Do not use Propofol 10 mg/ml:**

- in patients of 16 years of age or younger for sedation in intensive care
- if you are allergic (hypersensitive) to the Propofol active substance or to any of the excipients
- if you are allergic to peanut or soya. Propofol 10 mg/ml contains Soya oil.

#### **Take special care with Propofol 10 mg/ml**

- when you suffer from epilepsy (see point 4, "Possible side effects")

- when you suffer from reduced heart, lung, kidney or liver function
- when you have a low blood volume
- if you are feeling weak or debilitated
- when you have large quantities of fat in your blood or when you have problems processing or converting fat
- when you suffer from high pressure in your head
- when you suffer from low blood pressure
- when you use other medicinal products besides Propofol 10 mg/ml (see point 2.5 "Interaction with other (medicinal) products")
- with severe obesity
- when you suffer from a disease that is based on a disorder in the production of the red blood colouring (hereditary acute porphyria) and are treated at the same time with lidocaine as a local painkiller
- when you are undergoing treatment with which current surges are conducted through the brain (electroconvulsive therapy)
- when you receive intravenous lipids at the same time

The use of Propofol 10 mg/ml is not recommended in newborn infants.

Special care should be taken following use of Propofol 10 mg/ml and an adequate period is needed before you are discharged to ensure a full recovery. It is advisable to be accompanied by an adult upon leaving the place of administration. Your doctor will advise you on when you can undertake skilled or hazardous tasks such as driving.

Your doctor can also decide to treat you with a certain product that has an effect on the central nervous system (anticholinergic). This is to reduce the risk of side effects, such as a delayed heartbeat (bradycardia) and insufficient contraction of the heart muscle (asystolia).

### **Using other medicines**

A combination of various medicinal products may have harmful effects.

Therefore always inform your doctor about the medicines you are using. Do not forget to mention the medicines you can obtain without a prescription

Products that may enhance the effect or side effect of propofol are:

- opiate containing medicinal products ( e.g. fentanyl); temporary respiratory arrest may occur and last longer.
- suxamethonium (a muscle relaxant) and neostigmine (a product to reverse the effect of muscle relaxants) slow heartbeat (bradycardia) and cardiac arrest may occur faster

### **Pregnancy and breast-feeding**

Do not use propofol during pregnancy and breast-feeding, because:

- Propofol 10 mg/ml crosses the placental barrier and may be harmful to the still unborn child.
- Studies in breast-feeding women have shown that propofol is excreted in small amounts into the milk. Breast-feeding should be stopped, and the breast milk discarded for 24 hours after administration.

### **Driving and using machines**

Propofol is a product that makes you sleepy. When the effects of propofol and the immediate effects of the surgery are still present:

- do not drive
- do not use tools and/or operate machines.

### **3. HOW TO USE PROPOFOL 10 MG/ML**

You will be given propofol by your doctor. The dose you are given will vary depending on your age, body weight and physical condition (see point 2, "Do not use"). 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).

In general most adults under the age of 55 years will be administered the following doses of Propofol 10 mg/ml:

- to anaesthetise: 1.5 to 2.5 mg/kg
- maintaining anaesthesia with the aid of an infusion: 4 to 12 mg/kg/hour.
- maintaining anaesthesia with the aid of repeated injections: 25 to 50 mg.
- as a sedative: 0.3 to 4.0 mg/kg/hour. The dose should not be more than 4.5 mg/kg/hour

Propofol 10 mg/ml is only intended for administration via a vein (intravenous use) and can be administered in two different ways:

- via an injection
- via an infusion

During the procedure your doctor will be monitoring your heart rate, blood pressure and breathing.

#### **If you use more Propofol 10 mg/ml than you should**

With an overdose you may experience reduced cardiac (heart) function and respiratory (breathing) function. Your doctor will take measures immediately.

#### **If you forget to take a dose**

When you suspect a dose has been skipped consult your doctor.

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

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Propofol 10 mg/ml can cause side effects, although not everybody gets them.

#### **Very common (more than 1 out of 10 persons):**

A feeling of pain at the site of injection (while the injection is being given, before you fall asleep).

#### **Common (more than 1 out of 100 persons and less than 1 out of 10 persons):**

- low blood pressure.
- slow heart rate.
- stopping breathing temporarily while the injection is being given

- headaches during recovery phase.
- feeling sick (nausea) and vomiting during the recovery phase.

**Uncommon (more than 1 out of 1,000 persons and less than 1 out of 100 persons):**

- very low blood pressure.
- formation of blood clots and inflammation of the veins

**Rare (more than 1 out of 10,000 persons and less than 1 out of 1,000 persons):**

- epileptic-like involuntary movements, including fits and arching of the back during induction, maintenance and recovery.

**Very rare occurrences (less than 1 out of 10,000 persons, including isolated reports):**

- allergic (hypersensitivity) reactions which includes swelling of the face and throat, difficulty in breathing or wheezing, itchy rash or redness of the skin and low blood pressure.
- severe abdominal pain (pancreatitis)
- fluid in the lungs
- high temperature (fever) after the operation
- being unconscious after the operation
- discolouration of urine after prolonged administration.
- sexual disinhibition

**Side effects of unknown frequency may include**

- extreme feeling of well-being (euphoric mood)
- involuntary movements
- enlargement of the liver.
- kidney failure
- heart failure or abnormal heart rhythm
- drug abuse
- abnormal heart trace on ECG
- breakdown of muscle cells (rhabdomyolysis).
- too much acid in your blood (metabolic acidosis).
- increased amounts of potassium in your blood (hyperkalaemia).
- high blood level of a type of fat called lipids (hyperlipidaemia).

If propofol is administered as a sedative in doses of over 4 mg/kg/hour at the intensive care unit in very rare cases the breakdown of muscle tissue may occur involving muscle cramps, fever and red-brown discolouration of the urine (rhabdomyolysis), acidification of the blood (metabolic acidosis), too much potassium in the blood (hyperkalaemia) or heart failure (insufficient pumping strength of the heart), sometimes with fatal result.

After concomitant use with lidocaine the following side effects may occur: dizziness, vomiting, drowsiness, seizures/fits (convulsions), delayed heartbeat (bradycardia) disorders in the heart rhythm (arrhythmias) and poor blood supply to the tissues (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.

The sedative effects of Propofol may last up to 12 hours so you are advised to be accompanied on the leaving the hospital.

## **5. HOW TO STORE PROPOFOL 10 MG/ML**

Keep out of the reach and sight of children.

Do not use Propofol 10 mg/ml after the expiry date (EXP) which is stated on the vial, bottle or package. The expiry date refers to the last day of that month.

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

Your doctor will store this medicinal product for you.

Shelf –life after dilution or after first opening the container.

Chemical and physical in-use stability has been demonstrated for 6 hours at 2 to 8°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use Propofol 10 mg/ml if you notice that it is not a white to slightly off-white emulsion.

Any unused solution must be discarded immediately after first use. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What PROPOFOL 10 MG/ML contains**

The active substance is Propofol. Each ml contains 10 mg Propofol.

The other ingredients are purified egg phosphatides; soya-bean oil; glycerol; sodium hydroxide; water for injection.

### **What PROPOFOL 10 MG/ML looks like and contents of the pack**

Propofol is a white to almost white emulsion for injection or infusion.

Propofol 10 mg/ml is available in 20 ml clear, colourless, glass ampoules and 20 ml, 50 ml and 100 ml clear, colourless, glass bottles with rubber tops and flip-off caps.

Following pack sizes are available:

20 ml ampoules in pack size of 5 ampoules.

20 ml ampoules in pack size of 25 ampoules.

20 ml vials in pack size of 5 vials.

20 ml vials in pack size of 25 vials.

50 ml vials in pack size of 1 vial.  
50 ml vials in pack sizes of 20 vials.

100 ml vials in pack size of 1 vial.  
100 ml vials in pack sizes of 10 vials.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### Marketing Authorisation Holder

Name: Hospira Enterprises B.V.  
Address: Ranstad 22-11, 1316 BN Almere  
Country: The Netherlands  
Telephone +31 (0)23 5560100  
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### Manufacturer

Name: Abbott Laboratories  
Address: Avenida de Burgos, 91, 28050, Madrid  
Country: Spain  
Telephone: +34 1 337 5200  
Telefax: +34 1 337 5306

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

Denmark	Propofol "Hospira"
Finland	Propofol Hospira
Ireland	Propofol 10 mg/ml, emulsion for injection or infusion
The Netherlands	Propofol Hospira

**This leaflet was last approved in May 2013**

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*Dotted line to indicate separation between Information for the user (above) and Information for the Health professional (below).*

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

**PACKAGE LEAFLET: INFORMATION FOR HEALTHCARE PROFESSIONAL**

**Propofol 10 mg/ml, emulsion for injection or infusion**

Propofol

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