Product Name: FRESENIUS PROPOVEN 2%	Territory:	Colour:	1. Draft 08.04.2020, 11:00		Variable Data:
Type of Packaging: PIL	Dosage: 20ml	● BLACK			
Material number: M080510/00	2-D-Matrix Code M080510/00				
Pharma-Code (Laetus) -	EAN Code:				
Dimension: 180 x 588 mm	Font: Arial Smallest Size: 8 Pt.		Operator: Roberto Grill		

Package leaflet: Information for the user

Fresenius Propoven 2%

emulsion for injection or 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 Fresenius Propoven 2% is and what it is used for

Fresenius Propoven 2% 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).

Fresenius Propoven 2% emulsion for injection or infusion is used to:
- induce and maintain general anaesthesia in adults, adolescents and children older than 3 years.
- sedate patients older than 16 years of age receiving artificial respiration in intensive care.
- sedate adults, adolescents and children older than 3 years during diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia.

2. What you need to know before you are given Fresenius Propoven 2%

Do not use Fresenius Propoven 2%

- 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 Fresenius Propoven 2% and if any of the subsequent mentioned applies to you or applied to you in the past.

You should not receive Fresenius Propoven 2%, 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, Fresenius Propoven 2% should be given with caution to elderly or weak patients.

Before receiving Fresenius Propoven 2%, 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 Fresenius Propoven 2%:
- heart failure
- when there is insufficient blood reaching the tissues (circulatory failure)
- severe breathing problems (respiratory failure)
- dehydration (hypovolaemia)
- seizures (epilepsy)

Fresenius Propoven 2% 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 Fresenius Propoven 2%.

Involuntary movements can occur during sedation with Fresenius Propoven 2%. 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 Fresenius Propoven 2% 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 Fresenius Propoven 2% emulsion for injection or infusion is not recommended for use in children younger than 3 years of age.
Fresenius Propoven 2% 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.

Other medicines and Fresenius Propoven 2%
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Fresenius Propoven 2%)
- Other anaesthetics, including general, regional, local and inhalational anaesthetics (Lower doses of Fresenius Propoven 2% 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)

Fresenius Propoven 2% with food, drink and alcohol
After you have been given Fresenius Propoven 2%, 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.
Fresenius Propoven 2% 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 Fresenius Propoven 2%.

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.

Fresenius Propoven 2% contains soya-bean oil and sodium
Fresenius Propoven 2% 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 Fresenius Propoven 2%

Fresenius Propoven 2% 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 Fresenius Propoven 2% 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 (0.5 - 1 ml Fresenius Propoven 2%Fresenius Propoven 2%) 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 three years of age
The use of Fresenius Propoven 2% emulsion for injection or infusion is not recommended in children younger than 3 years of age.
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 Fresenius Propoven 2% to make them go to sleep (induction of anaesthesia). In younger children 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 dose requirements may be higher.

For sedation during surgical and diagnostic procedures in children over 3 years of age with Fresenius Propoven 2% 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 Fresenius Propoven 2% infusion to the desired level of sedation. Most patients require 1.5 - 9 mg/kg/h propofol.

Fresenius Propoven 2% 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
Fresenius Propoven 2% 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). Fresenius Propoven 2% will be injected into a vein either manually or by electric pumps.

The following information is intended for healthcare professionals only:

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. 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.

Fresenius Propoven 2% emulsion for injection or infusion is administered undiluted intravenously by continuous infusion.

Fresenius Propoven 2% emulsion for injection or infusion must not be mixed with other solutions for infusion or injection. 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.

Fresenius Propoven 2% 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, Fresenius Propoven 2% 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.

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

When Fresenius Propoven 2% 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 your national reporting systems.

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

5. How to store Fresenius Propoven 2%

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 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 Fresenius Propoven 2% should be replaced 12 hours after opening of the vial.

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 Fresenius Propoven 2% emulsion for injection or infusion contains

- The active substance is propofol.

Each ml emulsion contains 20 mg propofol.
Each 20 ml vial contains 400 mg propofol.
Each 50 ml vial contains 1000 mg propofol.
Each 100 ml vial contains 2000 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 Fresenius Propoven 2% looks like and contents of the pack

Fresenius Propoven 2% is a white oil-in-water emulsion for injection or infusion.

Fresenius Propoven 2% is available in colourless glass vials. The glass vials are sealed with rubber stoppers.

<u>Pack sizes:</u>
Packs containing 10 glass vials with 20 ml emulsion
Packs containing 1 glass vial with 50 ml emulsion
Packs containing 10 glass vials with 50 ml emulsion
Packs containing 15 glass vials with 50 ml emulsion
Packs containing 10 glass vials with 100 ml emulsion

Not all pack sizes may be marketed.

Manufacturer:
Fresenius Kabi Austria GmbH
A-8055 Graz, Hafnerstrasse 36
Austria
Fresenius Kabi AB
S-75174 Uppsala, Rapsgatan 7
Sweden

This leaflet was last revised in February 2020

V001-GRAZ

Co-administration of other medicinal products or fluids added to the Fresenius Propoven 2% infusion line must

occur close to the cannula site using a Y-piece connector or a three-way valve.

Fresenius Propoven 2% emulsion for injection or infusion is not advised for general anaesthesia in children younger than 3 years of age since the 20 mg/ml strength is difficult to be titrated in small children due to the extremely small volumes needed. The use of Fresenius Propoven 1% should be considered in children between 1 month and 3 years of age if a dose less than e.g. 100 mg/h is expected.

Fresenius Propoven 2% 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 breaking the vial seal. Administration must commence without delay.

Asepsis must be maintained for both Fresenius Propoven 2% and the infusion equipment throughout the infusion period. Fresenius Propoven 2% must not be administered through a microbiological filter.

The use of a burette, drop counter, syringe pump or volumetric infusion pump to control the infusion rate is recommended when Fresenius Propoven 2% is infused.

As usual for fat emulsions, the infusion of Fresenius Propoven 2% via one infusion system must not exceed 12 hours. The infusion set for Fresenius Propoven 2% must be changed at least every 12 hours.

To reduce pain on the injection site, Fresenius Propoven 2% emulsion for injection or infusion should be administered in a larger vein and/or lidocaine injection solution may be administered before induction of anaesthesia with Fresenius Propoven 2% 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 Fresenius Propoven 2%.

FRESENIUS
KABI