APPROVED PATIENT INFORMATION LEAFLET

Scheduling status

S5

Product name, strength and pharmaceutical form

Fresenius Propoven 1 % (20 ml) Emulsion for Injection or Infusion

Fresenius Propoven 1 % (50 ml) Emulsion for Injection or Infusion

Fresenius Propoven 1 % (100 ml) Emulsion for Injection or Infusion

Propofol

Contains sugar (as Glycerol 22,5 mg/ml)

Read all of this leaflet carefully before you start using Fresenius Propoven 1 %.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What Fresenius Propoven 1 % is and what it is used for

Fresenius Propoven 1 % is a short-acting intravenous general anaesthetic. 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 1 % is used to:

- Help put you to sleep before an operation or other procedure
- Sedate you when receiving artificial respiration in an Intensive Care Unit (ICU) for a period of up to 72 hours.
- Sedate you during surgical and diagnostic procedures

2. What you need to know before Fresenius Propoven 1 % is administered to you

You should not be administered Fresenius Propoven 1 %

- if you have a known hypersensitivity (allergy) to propofol or to any of the excipients of Fresenius Propoven 1 % (listed in section 6)
- if you have an allergy to soya or peanut
- for sedation of children of all ages with croup or epiglottitis receiving intensive care
- Fresenius Propoven 1 % is not recommended in children under the age of 3 years.
- Fresenius Propoven 1 % must not be used for sedation of patients less than 16 years of age in the intensive care unit.

Warnings and precautions

Special care should be taken with Fresenius Propoven 1 %

You will be cared for by doctors trained in anaesthesia (or, if applicable, doctors trained to care for patients in the intensive care unit).

Your respiration will be depressed, but you will be cared for by a healthcare professional.

Fresenius Propoven 1 % must never be injected into the epidural or spinal space.

Avoid anticholinergic medicine (used for nausea, vomiting, bladder conditions) before the operation. Some examples are dicyclomine, propantheline).

Tell your doctor or healthcare provider before being given the injection if:

- you have fat metabolic disorders or are at risk to fat embolism
- you have heart failure, or other serious heart problems
- your body has lost lots of fluids (you are hypovolaemic)
- lung disease, severe breathing problems (respiratory failure)
- you have kidney or liver problems
- you are using medicines (such as propranolol) that also slows the heart rate
- you suffer from epilepsy (seizures), as it may increase the risk of convulsions (“fits”)
- you are receiving electroconvulsive therapy (ECT, a treatment for psychiatric problems)
- you have a raised pressure inside the skull (raised intracranial pressure), as you will have to be closely monitored
- you have mitochondrial disease; this is when the mitochondria in your cells are not producing enough energy
- insufficient blood reaches your tissues (circulatory failure)
- you use with other medicines that make breathing difficult
- you are elderly, debilitated, or have a neurological disorder.

Fresenius Propoven 1 % may increase the risk of:

- epileptic seizures (“fits”)
- 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 1 %.

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

Propofol infusion syndrome (PRIS) has been reported. It can lead to cardiac failure, rhabdomyolysis (breakdown of skeletal muscle), metabolic acidosis and kidney failure and may be fatal.

After receiving Fresenius Propoven 1 %, do not:

- go home unaccompanied.
- consume alcohol.
- Enter into legal/contractual decisions for 24 hours as the interference with daily activities may continue for up to 24 hours.

Other medicines and Propoven Fresenius 1 %

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Make sure your doctor knows if you are also taking/receiving any of the following medicines:

- Anticholinergic medicines (medicines used to treat e.g. painful cramps of organs, asthma or Parkinson's disease)
- Benzodiazepines (medicines used to treat anxiety)
- Strong painkillers (fentanyl or opioids)

- Painkillers (analgesics)
- Premedication (your anaesthetist will know which medicines can be influenced by Fresenius Propoven 1 %)
- Other anaesthetics, including general, regional, local and inhalational anaesthetics
- Alcohol containing medicines or beverages
- Suxamethonium (muscle relaxant)
- Neostigmine (medicine used to treat a disease called myasthenia gravis)
- Ciclosporin (medicine used to prevent transplant rejections)
- Rifampicin (medicine used to treat tuberculosis)
- Valproate (medicine used to treat epilepsy or mental disorders).

Pregnancy, breastfeeding and fertility

Do not use Fresenius Propoven 1 % if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving Fresenius Propoven 1 %.

Fresenius Propoven 1 % should normally not be given to pregnant women.

You should stop breastfeeding and discard any breastmilk for 24 hours after receiving Fresenius Propoven 1 %.

Driving and using machines

After having Fresenius Propoven 1 % you may still feel sleepy for some time.

You should not perform skilled tasks, such as driving and operating machines, for 24 hours after general anaesthesia.

Fresenius Propoven 1 % contains soya-bean oil and sodium.

Soya-bean oil can cause severe allergic reactions (see “You should not be administered Fresenius Propoven 1 %”). Tell your doctor if you know that you have allergic reactions to soya-bean oil or peanut.

Fresenius Propoven 1 % contains less than 1 mmol (23 mg) sodium per 100 ml, i.e. essentially ´sodium-free`.

3. How Fresenius Propoven 1 % will be administered

You will not be expected to give yourself Fresenius Propoven 1 %. It will be given to you by a person who is qualified to do so.

The dose will be adjusted depending on your condition and the indication.
Fresenius Propoven 1 % 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). Fresenius Propoven 1 % will be injected into a vein either manually or by electric pumps. An electric pump may be used to give the injection for long operations and for use in intensive care.

When used for sedation, Fresenius Propoven 1 % should not be administered for more than 72 hours.

For induction of anaesthesia, Fresenius Propoven 1 % is not recommended for neonates below the age of 1 month.

For maintenance of anaesthesia Fresenius Propoven 1 % is not recommended for children (neonates).

Administration of Fresenius Propoven 1 % via a TCI (target controlled infusion) system is restricted to induction and maintenance of general anaesthesia in adults. It is not recommended for use in

children or in the intensive care unit (ICU) sedation or sedation for surgical and diagnostic procedures.

If you received more Fresenius Propoven 1 % than you should

Since a healthcare provider will administer Fresenius Propoven 1 %, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of Fresenius Propoven 1 %

Since a healthcare provider will administer Fresenius Propoven 1 %, it is unlikely that the dose will be missed.

4. Possible side effects

Fresenius Propoven 1 % can have side effects.
Not all side effects reported for Fresenius Propoven 1 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Fresenius Propoven 1 %, please consult your healthcare provider for advice.

Tell your doctor immediately if you have the following side effects, which may occur less frequently:

- Serious allergic reaction which causes swelling of the lips, face and throat, difficulty in breathing, swollen and reddened skin, hot flushes
- Build up of fluid in the lungs which can make you feeling breathless (may also happen when you wake up)
- Inflamed pancreas (pancreatitis) which causes severe stomach pain
- Kidney failure
- Convulsions or fits.

If you have these serious side effects, you may need urgent medical attention and further hospitalisation.

Tell your doctor or healthcare provider if you notice any of the following side effects:

Frequent

- Headache
- Involuntary movements
- Slow or fast heartbeat
- Respiratory depression
- Low blood pressure
- Changes in your breathing pattern, cough, hiccups
- Feeling sick (nausea), being sick (vomiting)
- A feeling of pain at the site of the injection

Less frequent

- Twitching and shaking of your body, or fits (may also happen when you wake up)
- Dizziness, shivering, chills and sensations of cold
- Being unconscious after the operation
- Swelling and redness or blood clots at the vein along the injection site
- Unusual colour of urine (may also happen when you wake up)
- Fever following surgery
- Premature contractions in your heart's upper (atria) or lower (ventricles) chambers, syncope (loss of consciousness), changes in ECG
- Delayed epilepsy-like attacks. The delay period ranges from a few hours to several days
- Sexual disinhibition.

Frequency not known

- Infection after the operation, or other infections
- Feeling euphoric
- Feeling sexually aroused
- Medicine abuse
- Irregular heart beat, heart failure
- Hypertension (high blood pressure)
- Increase in liver size
- Breakdown of muscle cells (rhabdomyolysis)
- Increase in acidity of your blood, high potassium and fat levels in your blood
- Severe skin and tissue reaction following accidental application beside the vein.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist, or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form" found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Fresenius Propoven 1 %.

5. How to store Fresenius Propoven 1 %

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not refrigerate or freeze.

Protect from light. Do not remove from outer container until required for use.

Single dose vial. Unused portions should be disposed of by a healthcare provider.

Do not use after the expiry date stated on the carton and vial.

6. Contents of the pack and other information

What Fresenius Propoven 1 % contains

1 ml emulsion contains 10 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 1 % looks like and contents of the pack

Fresenius Propoven 1 % is a white, homogeneous emulsion. Do not use if two layers can be seen after shaking the emulsion.

Packs containing 5 glass ampoules or 5 glass vials with 20 ml emulsion for intravenous injection. Packs containing 1, 10 or 15 glass vials with 50- or 100-ml emulsion for intravenous infusion. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Limited, Stand 7, Growthpoint Business Park, 162 Tonetti Street, Halfway House

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Registration Numbers

Fresenius Propoven 1 % (20 ml): 41/2.1/1121

Fresenius Propoven 1 % (50 ml): 41/2.1/1122

Fresenius Propoven 1% (100 ml): 41/2.1/1123

Access to the corresponding Professional Information

The corresponding PI will be included in the medicine package.