Patient Information Leaflet for Human Medicine

SCHEDULING STATUS S5

Propofol 2 % (20 mg/ml) B. Braun

Propofol

Other ingredients include:

1 mL of emulsion contains:

Soya bean oil refined 50 mg

Sodium 0,030 mg

Read all of this leaflet carefully before you start taking Propofol B. Braun

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.

What is in this leaflet:

1. What Propofol B. Braun is and what it is used for
2. What you need to know before you are given Propofol B. Braun
3. How Propofol B. Braun will be given to you
4. Possible side effects
5. How Propofol B. Braun is stored
6. Contents of the pack and other information

1. What Propofol B. Braun is and what it is used for.

Propofol B. Braun 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 B. Braun is used to:

- Put you to sleep before an operation and keep you asleep during the operation
- Sedate patients older than 16 years for up to 72 hours when receiving artificial respiration in an intensive care unit.

2. What you need to know before you are given Propofol B. Braun

Propofol B. Braun should not be administered

- If you are allergic to propofol, soya, peanut or any of the other ingredients of this medicine (see section 6)
- In patients of 16 years of age or younger for sedation during intensive care
- In patients younger than 3 years of age
- For sedation of children of all ages with croup or epiglottitis (inflammation of the glottis).

Warnings and precautions

Special care should be taken with Propofol B. Braun

Tell your doctor or health care provider before being given the injection:

- If you if you have a mitochondrial disease (a genetic disorder)
- If you have a disorder in which your body does not handle fat properly
- If you have any other health problems which require much caution in the use of fat emulsions
- If your blood volume is too low because you have lost a lot of fluid (hypovolaemia)
- If you are very weak (debilitated) or have heart, kidney or liver problems
- If you have high pressure within in the skull

- If you have problems with your breathing
- If you have epilepsy.

Please tell your doctor if you have one of these diseases or conditions.

If you are receiving other lipids by a drip into your vein at the same time your doctor will pay attention to your total daily fat intake.

Children and adolescents

Propofol B. Braun should not be used in children < 3 years of age. This medicine must not be used in patients of 16 years of age or younger for sedation for intensive care (see section ‘Do not use Propofol B. Braun’).

Other medicines with Propofol B. Braun:

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

Propofol has effectively been used with different regional anaesthesia techniques that only numb a part of your body (epidural and spinal anaesthesia).
Additionally, safe use has been demonstrated in combination with

- Drugs you receive before surgery
- Other medicines like muscle relaxing drugs
- Anaesthetic drugs that can be inhaled
- Pain killers.
- Psychoactive medicines
- Blood pressure medicines

- Medicines used to prevent nausea and vomiting.

However your physician may give you lower doses of propofol if general anaesthesia or sedation is needed as a supplement to regional anaesthesia techniques.
Make sure your doctor knows if you are also taking/receiving any of the following medicines:

- Rifampicin (is an antibiotic used to treat several types of bacterial infections, including tuberculosis)
- Valproate (medicine used to treat seizures)
- Benzodiazepines (tranquiliser, medicine used to treat anxiety, insomnia and seizures)
- Metoclopramide (medicine used to treat gastrointestinal issues).

Propofol B. Braun with alcohol

You should avoid alcohol until you are fully recovered. Your doctor will advise you further on the consumption of alcohol before and after the use of Propofol B. Braun.

Pregnancy, breastfeeding and fertility

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 health care provider for advice for taking this medicine.

Propofol B. Braun should not be used during pregnancy. It crosses the placenta and may depress the vital functions of the newborn.
However, your doctor may use propofol during an induced abortion (a process to end a pregnancy).

If you are breast-feeding your child you should stop nursing and discard breast milk for 24 hours after you have received Propofol B. Braun.

Driving and using machines

You should not drive or operate machinery for a while after you have had an injection or infusion of Propofol B. Braun.

Your doctor will advise you

- if you should be accompanied when you are leaving
- when you can drive and use machinery again
- on the use of other tranquillising medicines (e.g. tranquillizers, strong pain killers, alcohol).

Propofol B. Braun contains sodium and soya-bean oil

Propofol B. Braun contains less than 1 mmoℓ sodium (23 mg) in 100 mℓ that is to say essentially ‘sodium free’.

Propofol B. Braun contains soyabean oil. If you are allergic to peanut or soya, do not use this medicine.

3. How PROPOFOL B. BRAUN will be given to you

Propofol B. Braun will only be given by anaesthetists or by specially trained doctors in an intensive care unit.

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).

The doctor will also observe limits of the time of application, if necessary.
You will receive Propofol B. Braun by intravenous injection or infusion that is, through a needle or small tube placed in one of your veins.

Your circulation and breathing will be constantly monitored while you are being given the injection or infusion.

Your doctor will tell you how long your treatment with Propofol B. Braun will last. If you have the impression that the effect of Propofol B. Braun is too strong or too weak, tell your doctor or pharmacist.

If you take more Propofol B. Braun than you should

Since a health care provider will administer Propofol B. Braun he/ she will control dosage. However, in the event of over dosage your doctor will manage over dosage.

4. Possible side effects

Propofol B. Braun can have side effects.

Not all side effects reported for Propofol B. Braun are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Propofol B. Braun, please consult your healthcare professional for advice.

If any of the following happens, while you are receiving Propofol B. Braun a doctor must be called immediately, in order to stop administration of Propofol B. Braun

- Swelling of lips, face, throat, difficulty breathing or red, itchy skin, low blood pressure
- Rapid and shallow breathing, confusion and fatigue
- Changes in your heart rhythm, chest pain, swelling in legs

- Muscle weakness, pain and dark red or brown urine.

These are all very serious side effects, you may have had a serious reaction to B. Braun Propofol

Tell your doctor if you notice any of the following

Frequent side effects:

- Low or high blood pressure
- Too low heartbeat
- Pain at the injection site occurring during the first injection. Injection of lidocaine (a local anaesthetic) and propofol at the same time also helps to reduce the pain at the injection site
- Short interruption of breathing
- Headache during the time of recovery
- Sickness or vomiting during the time of recovery.

Less Frequent side effects:

- Convulsions like in epilepsy
- Inflammation of veins at the injection site
- Water on the lungs (lung oedema) after administration of propofol – you may experience difficulty breathing, wheezing
- Inflammation of the pancreas – you may experience stomach pain, fever, nausea, vomiting
- Loss of sexual control during the time of recovery
- Abnormal colour of urine after longer lasting administration of propofol
- Cases of fever after an operation
- Tissue damage can occur if the medicine is accidentally injected outside if a vein.

Frequency unknown:

- Involuntary twitching and jerking movements
- Abnormally good mood
- Drug abuse and drug dependence.

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

Reporting of side effects

If you get 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 via https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Propofol B. Braun

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Store all medicines out of reach of children.

Do not use this medicine after the expiry date which is stated on the label and the carton after EXP. The expiry sate refers to the last day of that month.

Do not freeze.

Propofol B. Braun must be used immediately after opening the vial.

Do not use Propofol B. Braun if two separate layers can be seen after shaking the product.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage system (e.g toilets).

Ask your pharmacist how to throw away medicines you no longer use.

6. Contents of the pack and other information

What Propofol B. Braun contains

The active substance is:

Each ml of Propofol B. Braun contains 20 mg of propofol

The other ingredients are:

Soya-bean oil refined

Medium-chain triglycerides

Egg phospholipids for injection

Glycerol

Sodium oleate

Water for injections.

What Propofol B. Braun looks like and contents of the pack

It is an emulsion for injection or infusion. It is a milky-white oil-in water emulsion.

It comes in glass bottles of 50 ml, available in packs of one or 10 bottles.

Not all pack sizes may be marketed.

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