Patient Information Leaflet for Human Medicines

SCHEDULING STATUS

S5

PATIENT INFORMATION LEAFLET

PROPOFOL 0,5 % (5 mg/ml) B. BRAUN

Propofol

Other ingredients include:

1 mL of emulsion contains:

Soya bean oil refined 50 mg

Sodium 0,030 mg

Sugar free

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.
- Sedate you during diagnostic and surgical procedures.

2. What you need to know before 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 Propofol B. Braun (listed in section 6).
- If your child is under the age of 3 years
- For sedation during intensive care.
- For sedation of children of all ages with croup or epiglottitis receiving intensive care.

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 generic 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.

Interference with daily activities may continue for up to 24 hours and no legal / contractual decisions should be entered into for 24 hours after receiving anaesthetic / conscious sedation.

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 under 3 years of age.

Taking 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.

Always tell your doctor 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.

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.

PROPOFOL B. BRAUN contains sodium and soya-bean oil

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

PROPOFOL B. BRAUN contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

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.

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 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 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** and inform your doctor 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 **PROPOFOL B. BRAUN**

Tell your doctor if you notice any of the following:

Frequent side effects:

- Low or high blood.
- Flushing
- 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
- Hiccups

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 of 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 5 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

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

It comes in glass ampoules of 20 ml, available in packs of 5 ampoules.

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