

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

B Braun Propofol 1 % (10 mg/ml) emulsion for intravenous injection or infusion
(Propofol)

Read all of this leaflet carefully before you are given B Braun Propofol 1 % (10 mg/ml)

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

What is in this leaflet:

1. What **B Braun Propofol 1 % (10 mg/ml)** is and what it is used for
2. What you need to know before you are given **B Braun Propofol 1 % (10 mg/ml)**
3. How to use **B Braun Propofol 1 % (10 mg/ml)**
4. Possible side effects
5. How to store **B Braun Propofol 1 % (10 mg/ml)**
6. Contents of the pack and other information

1. What B Braun Propofol 1 % (10 mg/ml) is and what it is used for

B Braun Propofol 1 % (10 mg/ml) contains a medicine called propofol. This 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).

B Braun Propofol 1 % (10 mg/ml) will be given to you as an injection by a doctor.

In adults and children over 3 years of age it is used to:

- Help put you to sleep before an operation or other procedure
- Keep you asleep during an operation or other procedure
- In people over 16 years of age it is also used to:

Sedate you when receiving artificial respiration in an Intensive Care Unit (ICU).

2. What you need to know before you are given B Braun Propofol 1 % (10 mg/ml)

B Braun Propofol 1 % (10 mg/ml) should not be administered to you:

- If you are allergic to propofol, soya, peanuts, or any of the other ingredients of this medicine (listed in section 6)
- If you are 16 years of age or younger for sedation in intensive care.

If any of the above apply to you or you are not sure, talk your doctor, anaesthetist, or nurse.

Warnings and precautions

B Braun Propofol 1 % (10 mg/ml) is not recommended in children aged less than 3 years.

Talk to your doctor, or health care provider before **B Braun Propofol 1 % (10 mg/ml)** is administered to you:

- If you have ever had a fit or convulsion
- if you have ever been told that you have very high levels of fat in your blood
- if you have ever been told that your body has problems using fat
- if you have any other health problems, such as problems with your heart, breathing, kidneys or liver
- if you have serious head injuries
- if you have a low protein concentration in your blood (hypoproteinaemia)
- if you have a mitochondrial disease
- if your blood volume is too low (hypovolaemia)
- if you have high pressure within in the skull
- if you are undergoing some procedures where spontaneous movements are particularly undesirable.

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.

Propofol will be administered to you by a physician trained in anaesthesia or intensive care. You will be constantly monitored during anaesthesia and waking-up time.

If you experience signs of the so called 'propofol infusion syndrome' (for a detailed list of the symptoms see the end of section 4 'Possible side effects, A doctor must be called immediately if any of the following happens') your doctor will immediately stop the dosage of propofol.

Other medicines and B Braun Propofol 1 % (10 mg/ml):

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

Tell your doctor if you are taking or using any of the following medicines:

- Rifampicin – used for tuberculosis (TB)
- Valproate – used in the treatment of epilepsy, bipolar disorder
- Benzodiazepine tranquilisers (medicines used for anxiety, as muscle relaxants, sedatives, anaesthetics, and as supportive medication for withdrawal from alcohol)
- Local anaesthetics
- Fentanyl – used to treat chronic breakthrough pain)
- Cyclosporin (used after organ transplant to reduce the activity of the patient's immune system.

These can all affect or be affected by the action of **B Braun Propofol 1 % (10 mg/ml)**.

B Braun Propofol 1 % (10 mg/ml) with alcohol

You should not drink alcohol just before you are receiving or just after you have received B Braun Propofol 1% (10 mg/ml).

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 before taking this medicine.

B Braun Propofol 1% (10 mg/ml) should not be administered to you if you are pregnant as it may harm your baby.

If you are breast-feeding your child, you should stop nursing and discard breast milk for 24 hours after you have received **B Braun Propofol 1% (10 mg/ml)**. Studies in breast-feeding women showed that propofol is excreted in small amounts into the milk.

Driving and using machines

After been administered with **B Braun Propofol 1 % (10 mg/ml)**, 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.

Ask your doctor when you can start doing these activities again and when you can go back to work.

B Braun Propofol 1 % (10 mg/ml) contains soya oil:

If you are allergic to peanut or soya, B Braun Propofol 1 % (10 mg/ml) should not be administered to you.

3. How to use B Braun Propofol 1 % (10 mg/ml)

B Braun Propofol 1 % (10 mg/ml) will only be given by anaesthetists or by specially trained doctors in an intensive care unit.

B Braun Propofol 1 % (10 mg/ml) is for intravenous use only and it will be given to you as an injection into a vein. This is usually in the back of your hand or in your forearm.

- The doctor will give you the injection through a fine plastic tube called a 'cannula'
- The doctor can also use an electric pump to control how fast the injection is given. This may be done if you are having a long operation or if you are in an Intensive Care Unit.

Your doctor will decide on the suitable dose based on your age, body weight, physical condition and the level of sleepiness or sleep that you need. The doctor will give you the correct dose to start and to maintain 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.

If you take more B Braun Propofol 1 % (10 mg/ml) than you should

Since a health care provider will administer B Braun Propofol 1 % (10 mg/ml), he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

B Braun Propofol 1 % (10 mg/ml) can have side effects.

Not all side effects reported for B Braun Propofol 1 % (10 mg/ml) are included in this leaflet. Should your general health worsen or if you experience any untoward effects after having been administered with B Braun Propofol 1 % (10 mg/ml), please consult your doctor, pharmacist, or other healthcare professional for advice.

The following side effects can happen during anaesthesia (while the injection is being given to you or when you are sleepy or asleep) or when you wake up. Your doctor will be looking out for these. If they happen, your doctor will give you appropriate treatment.

Frequent side effects:

- Pain at the site of the injection. The pain may be reduced by injecting propofol into larger veins of the forearm. Injection of lidocaine (a local anaesthetic) and propofol at the same time also helps to reduce the pain at the injection site

- Low blood pressure
- Changes in your breathing pattern
- Slow heartbeat
- Feeling sick (nausea)
- Being sick (vomiting)
- Headache
- Sweating, shaking and feeling anxious
- Flushing of the skin.

Less frequent side effects:

- Twitching and shaking of your body, or a fit
- Unusual colour of urine
- Allergic reactions which can include swelling of the face, tongue or throat, wheezing, flushing and falling blood pressure
- Stopping of your heartbeat
- Build-up of fluid in the lungs which can make you very breathless
- Swelling and redness along a vein or blood clots
- Feeling sexually aroused
- High temperature (fever)
- Redness or soreness where the injection was given
- Tissue damage
- Heart failure
- Inflamed pancreas (pancreatitis) which causes severe stomach pain
- Too much acid in your blood. This may make you breathe more quickly.
- Increased amount of potassium in your blood
- High blood level of a type of fat called lipids
- Abnormal heartbeat
- Unconsciousness

- Kidney failure.

Frequency not known:

- A feeling of pain at the site of the injection
- Swelling at the site of injection
- Prolonged, often painful erection (priapism)
- Enlargement of the liver
- Euphoric mood
- Involuntary movements
- Abnormal ECG
- Breakdown of muscle cells (rhabdomyolysis)
- Propofol infusion syndrome (PRIS): This is characterized as by the following symptoms: breakdown of muscle tissue, accumulation of acidic (sour) substances in the blood, abnormally high blood potassium level, high blood fat levels, abnormalities in the electrocardiogram (Brugada-type ECG), liver enlargement, irregular heartbeat, kidney failure and heart failure
- Drug abuse/ drug dependence
- Failure of the heart.

If any of these side effects persist or worsen, please inform your doctor as soon as possible.

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/8>. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store B Braun Propofol 1 % (10 mg/ml)

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

The doctor and hospital pharmacist are responsible for storing, using and disposing of **B Braun Propofol 1 % (10 mg/ml)** correctly.

Store **B Braun Propofol 1 % (10 mg/ml)** at or below 25°C. Do not freeze. Keep the ampoules in the carton to protect from light.

Use immediately after opening the ampoule. Any unused emulsion must be thrown away at the end of administration.

Do not use **B Braun Propofol 1 % (10 mg/ml)** after the expiry date printed on the carton.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What B Braun Propofol 1 % (10 mg/ml) contains

The active substance is propofol. There is 10 mg of propofol in each millilitre.

The other ingredients are Soya-bean oil, refined; Triglycerides, medium chain; Egg phospholipids for injection; Glycerol; Sodium oleate; Water for injection.

What B Braun Propofol 1 % (10 mg/ml) looks like and contents of the pack

B Braun Propofol 1 % (10 mg/ml) is a white, milky oil-in-water emulsion.

It is packed into:

20 ml type I, colourless glass ampoules which are packed into cartons.

50 ml colourless Type II glass bottles closed with a Type I bromobutyl rubber stopper and an aluminium cap with flip-off polypropylene centre portion.

100 ml colourless Type II glass bottles closed with a Type I bromobutyl rubber stopper and an aluminium cap with flip-off polypropylene centre portion.

Pack sizes:

5 x 20 ml ampoules

10 x 50 ml glass bottles

10 x 100 ml glass bottles

Not all packs or pack sizes are necessarily marketed.

HOLDER OF THE CERTIFICATE OF REGISTRATION

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