



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
PROPOFOL INJECTION
Propofol 10mg/ml

Read this leaflet carefully before you start taking this medicine.

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

1. What Propofol Injection is and what it is used for
2. What you need to know before you use Propofol Injection
3. How to use Propofol Injection
4. Possible side effects
5. How to store Propofol Injection
6. Contents of the pack and other information

1. WHAT PROPOFOL INJECTION IS AND WHAT IT IS USED FOR

Propofol 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.

Propofol will be given to you as an injection by a doctor.

In adults and children over 1 month of age, it is used to:

- Help put you to sleep **before** an operation or other procedures.
- Keep you asleep **during** an operation or other procedures.
- Sedate you during diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PROPOFOL INJECTION

Do not take Propofol Injection:

- If you are allergic to propofol or any of the other ingredients of this medicine
- If you are allergic to peanut or soya. This is because Propofol contains soya oil, which may lead to allergies in patients with soya bean allergy
- If you are 16 years of age or younger for sedation in intensive care.

If any of the above applies to you, do not take Propofol and tell your doctor, anaesthetist or nurse.

If you are not sure, talk to one of these people before taking Propofol.

Warnings and precautions

The use of Propofol is not recommended in newborn infants.

Talk to your doctor, anaesthetist or nurse before using Propofol.

Before you have this medicine, tell your doctor, anaesthetist or nurse



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- 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 metabolising fat.
- If your body has lost lots of water (you are dehydrated).
- If you have any other health problems, such as problems with your heart, breathing, kidneys or liver.
- If you have been generally unwell for some time.
- If you have mitochondrial disease

Studies in young animals and clinical data suggest that repeated or lengthy use of general anaesthetics or sedation drugs in children younger than 3 years or in pregnant women during their third trimester may have negative effects on the development of the child's brain. Parents and caregivers should discuss the benefits, risks, timing and length of surgery or procedures requiring anaesthetics or sedation with your doctor.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before taking Propofol.

Other medicines and Propofol

Tell your doctor if you are taking or have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

Tell your doctor, anaesthetist or nurse if you are taking any of the following medicines:

- Rifampicin (for tuberculosis - TB)

Pregnancy and breast-feeding

Do not take Propofol if you are pregnant unless absolutely necessary.

Studies have shown that small amounts of propofol can pass into breast milk. Therefore, you should not breastfeed your baby for 24 hours after taking propofol.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

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.

3. HOW TO TAKE PROPOFOL INJECTION

You will be given Propofol by a doctor. It will be given to you as an injection into a vein.



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This is usually in the back of your hand or in your forearm.

- The doctor will give you the injection using a needle or 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.

The dose of Propofol varies from one patient to another. The amount of propofol that you need depends on your age, size, physical fitness and the level of sleepiness or sleep that you need. The doctor will give you 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. These effects are normally mild or moderate and often disappear after a short time.

4.1 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)

- Low blood pressure.
- Changes in your breathing pattern.
- Slow heartbeat.

Rare (may affect up to 1 in 1,000 people)

- Twitching and shaking of your body, or a fit (may also happen when you wake up).
- Unusual colour of urine (may also happen when you wake up).

Very rare (may affect up to 1 in 10,000 people)

- Allergic reactions.
- Stopping of your heart beat.
- Build up of fluid in the lungs which can make you very breathless (may also happen



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when you wake up).

Not known: frequency cannot be estimated from the available data

- Shallow breathing.
- Prolonged, often painful penile erection (priapism).

4.2 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)

- Feeling sick (nausea).
- Being sick (vomiting).
- Headache.

Uncommon (may affect up to 1 in 100 people)

- Swelling and redness along a vein or blood clots.

Very rare (may affect up to 1 in 10,000 people)

- Feeling sexually aroused.
- High temperature (fever).
- Redness or soreness where the injection was given.
- Being unconscious after the operation. (When this has happened, the patients have recovered without problems.)
- Tissue damage.

Not known: frequency cannot be estimated from the available data

- A feeling of pain at the site of the injection.
- Swelling at the site of injection.
- Prolonged, often painful penile erection (priapism).

4.3 Other possible side effects

The following side effects have been seen when propofol was used in intensive care at higher doses than recommended.

Very rare (may affect up to 1 in 10,000 people)

- 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 heart beat.
- Enlargement of the liver.



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- Kidney failure.

The following side effects have been seen in children in intensive care when propofol was stopped suddenly.

Common (may affect up to 1 in 10 people)

- 'Withdrawal symptoms'. These include unusual behaviour, sweating, shaking and feeling anxious.
- Flushing of the skin

Not known: frequency cannot be estimated from available data

- Euphoric mood.
- Involuntary movements.
- Abuse and dependence on propofol, mostly by healthcare professionals.
- Abnormal ECG.
- Breakdown of muscle cells (rhabdomyolysis)

If you think you have a side effect or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

Reporting of side effects

If you get any side effect, talk to your doctor, pharmacist or nurse. This includes any possible side effect not listed in this leaflet.

5. HOW TO STORE PROPOFOL INJECTION

- Keep this medicine out of the sight and reach of children.
- Store below 30°C
- Do not freeze
- Do not use Propofol Injection after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION.

What PROPOFOL INJECTION contains

Each ml of Propofol Injection contains 10mg of Propofol.

What PROPOFOL INJECTION looks like and contents of the pack

Milky white emulsion in 10x5ml Ampoules packed in an inner carton

SUPPLIER AND MANUFACTURER

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