

PROVIVE 1%

Propofol

Emulsion for Intravenous Injection or Infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about this medicine.

It does not contain all the available information. It does not take the place of talking to your doctor or anaesthetist.

All medicines have risks and benefits. Your doctor or anaesthetist has weighed the risks of you being given Provive 1% against the benefits it is expected to have for you.

If you have any concerns about being given this medicine, ask your doctor or anaesthetist. Keep this leaflet. You may need to read it again.

If you have any concerns about being administered this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What PROVIVE 1% is used for and how it works

General anaesthesia

Provive 1% contains propofol, which is used as a short-acting general anaesthetic in adults, and children aged 3 years or older.

A general anaesthetic is a medicine which produces general anaesthesia. Provive MCT-LCT 1% is short-acting, which means that patients go to sleep quickly, usually within 30 seconds of receiving the medication, but then wake up quickly as it wears off.

Provive 1% can be used for very short operations when only one injection is needed. Provive 1% can be used throughout longer operations if more is given as repeated doses. Provive 1% can also be used to start off anaesthesia (induction anaesthesia). This means the anaesthetist may change over to another anaesthetic once sleep is induced.

Sedation

Provive 1% can be given to adults and adolescents over 16 years of age in lower doses if they need to be sedated or sleepy, but do not need the heavy sleep of anaesthesia. This type of sedation may be required during certain tests or procedures.

Provive 1% can also be used in intensive care wards for adults and adolescents over 16 years of age who are being ventilated (on a breathing machine) to keep them sedated.

Ask your doctor or anaesthetist if you have any questions about why this medicine has been prescribed for you. Your doctor or anaesthetist may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 3 years for general anaesthesia. This medicine must not be used for children 16 years of age and under for sedation during tests or procedures, or for sedation in the intensive care ward.

Before you are given PROVIVE 1%

When you must not be given PROVIVE 1%

You must not be given Provive 1% if you have an allergy to:

- any medicine containing propofol;
- any of the other ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Before you are given PROVIVE 1%

Tell your doctor or anaesthetist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or anaesthetist if you have or have had any of the following medical conditions:

- epilepsy (fits or convulsions)
- heart-disease
- respiratory (breathing) problems
- liver or kidney disease
- very high blood fat levels or disorders of fat metabolism (this warning applies to very rare conditions, not the more common high blood cholesterol)
- general debility for some time (feebleness, weakness or loss of strength).

Tell your doctor or anaesthetist if you are pregnant or if you intend to become pregnant or are breast-feeding.

Provive 1% is not recommended for use during pregnancy or breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor or anaesthetist about any of the above, tell them before you are given Provive 1%.

Taking other medicines

Tell your doctor, anaesthetist or pharmacist if you are taking or using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and propofol may interfere with each other. These include:

- strong pain relievers;
- medicines used to produce calmness or to help you to sleep;
- some medicines used to treat anxiety;
- some medicines used to treat epilepsy such as barbiturates.

Your doctor, anaesthetist or pharmacist may have information on medicines to be careful with or avoid when you are given this medicine.

How is PROVIVE 1% to be given

How much will be given:

Your doctor or anaesthetist will decide how much Provive 1% you are to be given. This will depend on your age and other factors such as your weight and the duration of your

procedure. The dose will be adjusted to keep you at the right depth of sleep or sedation. The dose of Provive 1% needed for sedation is less than that needed for anaesthesia.

How will it be given?

Provive 1% is given by an injection into a vein, usually in the forearm or the back of the hand. It must only be given by a doctor or anaesthetist. Each vial is used for one dose in one patient only. Any remaining contents must be discarded after each dose.

Overdose

As Provive 1% is given to you under the supervision of your doctor or anaesthetist, it is very unlikely that you will receive too much. Your doctor or anaesthetist has information on how to recognise and treat an overdose.

Ask your doctor or anaesthetist if you have any concerns.

While you are being given PROVIVE 1%

Things to be careful of

Do not drive a car or operate machinery for at least one day after you have been given Provive 1%.

As with other anaesthetics, Provive 1% may cause impairment of skilled tasks, such as driving or operating machinery, for some time after you have been given it. Make sure you know how you react to Provive 1% before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy or dizzy.

Ask your doctor when you can return to work involving driving, or operating machinery or heavy equipment.

Side Effects

This medicine helps provide anaesthesia or sedation for most people, but it may have unwanted side effects in a few people. Tell your doctor or anaesthetist as soon as possible if you do not feel well after you have been given Provive 1%.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or anaesthetist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- pain, heat or tingling at the injection site;
- flushing of the skin;
- dizziness;
- nausea or vomiting, cough, headache, shivering, restlessness or mood changes when you are waking up from the anaesthetic;
- hiccupping or stopping breathing very briefly.

The above list includes the more common side effects of your medicine. They are usually mild and short lived.

Date of preparation of this leaflet: January 2019

Tell your doctor as soon as possible if you notice any of the following:

- slow, fast or irregular heart beat;
- convulsions (fitting);
- signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin;
- severe pain in the upper stomach;
- temporary paralysis or weakness of the muscles.

The above list includes serious side effects. These side effects are rare. Some of the side effects of Provive 1% may occur whilst you are asleep or sedated. Your doctor or anaesthetist is trained to manage these reactions in the unlikely event that they occur. For example, if you are sleeping too deeply and your blood pressure is too low or you need help breathing, your anaesthetist may reduce the dose of Provive 1%. If your sleep is too light and you move or wriggle a bit, the dose may be increased. If your heart rate becomes too slow or irregular other medicines may be needed. Tell your doctor or anaesthetist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After using Provive 1%

Storage

Provive 1% will be stored in the pharmacy or on the ward. Provive 1% is kept in a cool dry place where the temperature stays below 30°C. Do not freeze. Protect from light.

Any unused Provive 1% from the opened vial will be discarded.

Product Description

What does PROVIVE 1% look like?

Provive 1% is a milky, white liquid in a clear glass vial with an aluminium and violet plastic cap.

It is available in 20 mL, 50 mL and 100 mL vials.

Ingredients

Active ingredients:

- propofol 10 mg/mL.

Inactive ingredients:

- Soya oil
- Glycerol
- Lecithin egg
- Sodium oleate
- Sodium hydroxide
- Water for injections

Provive 1% does not contain lactose, sucrose, gluten, tartrazine or other azo dyes.

Name and Address of Sponsor

Baxter Healthcare Pty Ltd
1 Baxter Drive Old
Toongabbie, NSW 2146
Australia

Australian Registration numbers:

Provive 1% 20 mL: AUST R 118938

Provive 1% 50 mL: AUST R 118939

Provive 1% 100 mL: AUST R 118940