

PROVIVE 1%

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given Provive 1%?

Provive 1% contains the active ingredient Propofol. Provive1 % is used for short acting intravenous anaesthetic agent suitable for induction and maintenance of general anaesthesia in adults and in children aged three years and older.

For more information, see Section [1. Why am I being given Provive 1%?](#) in the full CMI.

2. What should I know before being given Provive 1%?

Do not use if you have ever had an allergic reaction to Propofol or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before being given Provive 1%?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Provive 1% and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is Provive 1% 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.

More instructions can be found in Section [4. How is Provive 1% given?](#) in the full CMI.

5. What should I know while being given Provive 1%?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you have received Provive 1%.
Things you should not do	<ul style="list-style-type: none">Do not take any other medicines whether they require a prescription or not without first telling your doctor.You should not be released from medical care until you have completely recovered from anaesthesia, and then you should be accompanied by a responsible adult.
Driving or using machines	<ul style="list-style-type: none">Do not drive a car or operate machinery or heavy equipment.Ask your doctor when you can return to work involving driving, or operating machinery or heavy equipment.
Drinking alcohol	<ul style="list-style-type: none">Do not drink alcohol as it can increase the effect of propofol.
Looking after your medicine	<ul style="list-style-type: none">Provive 1% in unopened containers should be stored below 30°C. Do not freeze.Keep in carton until use to protect contents from light. Use immediately after opening.

For more information, see Section [5. What should I know while being given Provive 1%?](#) in the full CMI.

6. Are there any side effects?

Some of the less serious side effects include Pain during injection, difficulty breathing, headache, feeling like fainting, feeling sick or vomiting. Serious side effects include swelling of the face, tongue or throat (allergic reaction), changes in heartbeat, strong drop in blood pressure, convulsive fits, unconsciousness, shock, blood clots, and symptoms associated with propofol infusion syndrome.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Provive 1%

Active ingredient(s): *Propofol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Provive 1%. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Provive 1%.**

Where to find information in this leaflet:

- [1. Why am I being given Provive 1%?](#)
- [2. What should I know before being given Provive 1%?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Provive 1% given?](#)
- [5. What should I know while being given Provive 1%?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given Provive 1%?

Provive 1% contains the active ingredient Propofol. Provive 1 % is a short acting intravenous anaesthetic agent suitable for induction and maintenance of general anaesthesia in adults and in children aged three years and older.

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.

2. What should I know before being given Provive 1%?

Warnings

You must not be given Provive 1% if:

- if you are allergic to propofol, soya or peanut or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You are allergic (hypersensitive) to soya or peanut
- to children 16 years or younger for sedation.

Check with your doctor if you:

- have any other medical conditions:
 - have epilepsy.

- have a very high blood fat level due to a rare disorder of fat metabolism.
- have low blood volume (hypovolaemia).
- have high pressure in your skull.
- are very overweight.
- have low blood pressure in the arteries.
- have any other health problems such as with your heart, circulation, breathing, kidneys or liver or if you have been generally unwell for some time.
- have any other health problems which require caution in the use of fat emulsions.
- are undergoing some procedures where spontaneous movements are particularly undesirable.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor or anaesthetist if you are pregnant or intend to become pregnant.

Talk to your doctor or anaesthetist if you are breastfeeding or intend to breastfeed. Provive1% is not recommended for use while you are breastfeeding.

It may be necessary to defer an operation or procedure, or use different anaesthetics if you are pregnant or breast feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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:

- Some medicines may depress your breathing or your blood circulation when combined with Propofol or prolong the effect of Propofol such as painkillers, benzodiazepine tranquillisers, narcotic gases, some local anaesthetics, fentanyl, other medicinal products usually given before operations. On the other hand, the sedative effect of some of these medicinal products may become stronger.
- Occurrence of a specific organic changes in the brain (leucoencephalopathy) has been reported in patients having received fat emulsions such as FRESOFOL 1% MCT/LCT together with cyclosporin (a medicine used to suppress rejection reactions after organ

transplantation and to suppress overreactions of the immune system).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Provive 1%.

4. How is Provive 1% 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 Provive 1% be given

- Provive 1% is given by an injection into a vein or by continuous infusion, 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.

If you are given too much Provive 1%

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 recognize and treat an overdose.

If you have any further questions on the use of this product, ask your doctor or anaesthetist.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given Provive 1%?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are receiving Provive 1%.

Things you should not do

- Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Driving or using machines

- 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

- It is not recommended that you drink alcohol while using Provive 1%.

Looking after your medicine

- Provive 1% in unopened containers should be stored below 30°C. Do not freeze.
- Follow the instructions in the carton on how to take care of your medicine properly.
- Keep in carton until use to protect contents from light. Use immediately after opening.

Keep out of the reach and sight of children.

When to discard Provive 1%

Do not use if the emulsion is separated or discoloured.

Any portion of the contents remaining after use should be discarded.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, hospital staff will take it to the pharmacy for safe disposal

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">feeling like faintinghaving difficulty breathingpain during injectionelation or euphoriaheadachesleepinessshivering	Speak to your doctor if you have any of these less serious side effects and they worry you.

<ul style="list-style-type: none"> feeling sick or vomiting fever after operation skin rash loss of sexual control abnormal colour of urine 	
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	hydroxide and Water for injections.
Potential allergens	Soya bean product

Do not take this medicine if you are allergic to any of these ingredients.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> swelling of face, tongue or throat irregular, too slow or changes in heartbeat, including up to heart failure strong drop in blood pressure convulsive fits unconsciousness shock breathlessness symptoms associated with Propofol infusion syndrome: muscle pain, high potassium, fat and acidic substances in your blood, abnormal ECG, liver enlargement, irregular heartbeat, kidney failure and heart failure inflammation of the pancreas blood clots water in the lungs (lung oedema) after administration of propofol 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

What Provice 1% looks like

Provice 1% is a white, oil in water emulsion supplied in a glass vial with a grey butyl rubber closure and aluminium and plastic violet flip-off seal.

Provice 1% is available in three presentations:

200 mg propofol in 20 mL: AUST R 118938 – packs of 5 vials

500 mg propofol in 50 mL: AUST R 118939 – packs of 1 vial

1000 mg propofol in 100 mL: AUST R 118940 – packs of 1 vial

Who distributes Provice 1%

Baxter Healthcare Pty Ltd

1 Baxter Drive Old Toongabbie

NSW 2146, Australia

Toll Free Number: 1800 229 837

www.baxterhealthcare.com.au

This leaflet was prepared in August 2025.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Provice 1% contains

Active ingredient (main ingredient)	Propofol
Other ingredients (inactive ingredients)	Soya oil, Glycerol, Egg lecithin, Sodium oleate, Sodium