

# PROPOFOL-LIPURO

## 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 PROPOFOL-LIPURO?

PROPOFOL-LIPURO contains the active ingredient propofol. PROPOFOL-LIPURO is a short-acting sleep-inducing medicinal product used as a general anaesthetic.

It is used to cause unconsciousness (sleep) so that surgical operations or other procedures can be performed. It may also be used to make you sleepy but not completely asleep.

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

### 2. What should I know before being given PROPOFOL-LIPURO?

Do not use if you have ever had an allergic reaction to propofol, soya or peanut 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 PROPOFOL-LIPURO?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with PROPOFOL-LIPURO 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 PROPOFOL-LIPURO given?

- PROPOFOL-LIPURO will only be given by an anaesthetist or by a specially trained doctor in an intensive care unit.
- The dose you are given will vary depending on your age, body weight and physical condition, to start and to sustain anaesthesia or to achieve the required level of sedation.

More instructions can be found in Section [4. How is PROPOFOL-LIPURO given?](#) in the full CMI.

### 5. What should I know while being given PROPOFOL-LIPURO?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you have received PROPOFOL-LIPURO.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not take any other medicines whether they require a prescription or not without first telling your doctor.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Do not drive or operate machinery until your doctor says it is safe.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Do not drink alcohol as it can increase the effect of propofol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• PROPOFOL-LIPURO should be kept in the pack until use, protected from light, in a cool dry place where the temperature stays below 25°C. Do not freeze.</li></ul>

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

### 6. Are there any side effects?

Common side effects include: Pain during injection, difficulty breathing, headache, feeling like fainting, feeling sick or vomiting. Other side effects may include: elation or euphoria, sleepiness, shivering, skin rash, loss of sexual control, fever after operation and abnormal colour of urine. 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.

# PROPOFOL-LIPURO

Active ingredient(s): Propofol

## Consumer Medicine Information (CMI)

This leaflet provides important information about using PROPOFOL-LIPURO. **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 PROPOFOL-LIPURO.**

Where to find information in this leaflet:

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

### 1. Why am I being given PROPOFOL-LIPURO?

PROPOFOL-LIPURO contains the active ingredient propofol. PROPOFOL-LIPURO is a short-acting general anaesthetic that can be given into the blood stream through a needle.

PROPOFOL-LIPURO is used to cause unconsciousness (sleep) so that surgical operations or other procedures can be performed. It may also be used to make you sleepy but not completely asleep. It is used in adults and children aged one month or older.

### 2. What should I know before being given PROPOFOL-LIPURO?

#### Warnings

**You must not be given PROPOFOL-LIPURO:**

- if you are allergic to propofol, soya or peanut or any of the ingredients listed at the end of this leaflet.
- to children younger than one month of age for general anaesthesia.
- to children 16 years or younger for sedation.

Always check the ingredients to make sure you can be given this medicine.

**Check with your doctor if you:**

- 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. If you experience signs of the so called "Propofol Infusion Syndrome (PRIS)", your doctor will decrease the dosage of propofol or switch to an alternative medicine. 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 if you are pregnant or intend to become pregnant.**

PROPOFOL-LIPURO should not be used during pregnancy.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.** PROPOFOL-LIPURO is not recommended for use while you are breastfeeding. If you are breast-feeding your child, you should stop nursing and discard breast milk for 24 hours after you have received PROPOFOL-LIPURO.

### 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 may interfere with PROPOFOL-LIPURO and affect how it works.**

Some medicines may depress your breathing or your blood circulation when combined with propofol or prolong the effect of propofol such as painkillers, benzodiazepine tranquilisers, 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.

When given together with Propofol, certain medicines used for muscle relaxation (suxamethonium) or as an antidote (neostigmin) may depress heart function.

Low blood pressure has been reported following anaesthetic induction with propofol in patients treated with rifampicin.

Lower propofol doses may be required in patients being treated with valproate or midazolam.

Occurrence of a specific organic change in the brain (leucoencephalopathy) has been reported in patients having received fat emulsions such as PROPOFOL-LIPURO together with ciclosporin (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 PROPOFOL-LIPURO.**

## 4. How is PROPOFOL-LIPURO given?

### How much is given

- PROPOFOL-LIPURO will only be given by an anaesthetist or by a specially trained doctor in an intensive care unit.
- PROPOFOL-LIPURO will usually be given by injection into a vein when used to induce general anaesthesia and by continuous infusion (a slower, longer injection) when used to maintain general anaesthesia. It may be given as an infusion either diluted or undiluted. When used as a sedative it will usually be given by infusion.
- 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 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).
- The doctor will also observe limits of the time of application, if necessary. PROPOFOL-LIPURO does not contain preservatives, so an infusion from one vial or bottle of PROPOFOL-LIPURO will not last longer than 12 hours.
- PROPOFOL-LIPURO will only be given for a maximum of 7 days.

### If you use too much PROPOFOL-LIPURO

It is unlikely that this will occur because the doses you receive are very carefully controlled.

If you were accidentally given an overdose, this could lead to depression of heart function, circulation and breathing. In this case your doctor will employ any necessary treatment immediately.

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

## 5. What should I know while being given PROPOFOL-LIPURO?

### Things you should do

Remind any doctor, dentist or pharmacist you visit that you are receiving PROPOFOL-LIPURO.

### 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

**Be careful before you drive or use any machines or tools until you know how PROPOFOL-LIPURO affects you.**

You should not drive or operate machinery for a while after you have had an injection or infusion of PROPOFOL-LIPURO. Your doctor will tell you how long you must wait and advise you before you drive or use machinery again.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

Alcohol and propofol make the sedative effects of each other stronger. Therefore, you should not drink alcohol just before or just after you have been given PROPOFOL-LIPURO.

### Looking after your medicine

- **Keep out of the reach and sight of children.**
- Do not use PROPOFOL-LIPURO after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.
- Keep the ampoules, vials and bottles in the outer carton in order to protect from light. Store below 25°C.
- Do not freeze.
- PROPOFOL-LIPURO must be used immediately after opening the ampoule, vial or bottle. Dilutions of PROPOFOL-LIPURO must be used immediately after preparation.
- Do not use PROPOFOL-LIPURO if two separate layers can be seen after shaking the product or if it is not milky-white.

### 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	What to do
<ul style="list-style-type: none"> <li>• feeling like fainting</li> <li>• having difficulty breathing</li> <li>• pain during injection</li> <li>• elation or euphoria</li> <li>• headache</li> <li>• sleepiness</li> <li>• shivering</li> <li>• feeling sick or vomiting</li> <li>• fever after operation</li> <li>• skin rash</li> <li>• loss of sexual control</li> <li>• abnormal colour of urine</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• swelling of face, tongue or throat</li> <li>• irregular, too slow or changes in heartbeat, including up to heart failure</li> <li>• strong drop in blood pressure</li> <li>• convulsive fits</li> <li>• unconsciousness</li> <li>• shock</li> <li>• breathlessness</li> <li>• 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</li> <li>• inflammation of the pancreas</li> <li>• blood clots</li> <li>• water in the lungs (lung oedema) after administration of propofol</li> </ul>	<p><b>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.</b></p>

**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](http://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 PROPOFOL-LIPURO 1% contains

<b>Active ingredient (main ingredient)</b>	Propofol 1 mL contains 10 mg of propofol
<b>Other ingredients (inactive ingredients)</b>	Soya oil, Medium-chain triglycerides, Egg lecithin, Glycerol, Sodium oleate, Water for injections
<b>Potential allergens</b>	Soya

### What PROPOFOL-LIPURO 2% contains

<b>Active ingredient (main ingredient)</b>	Propofol 1 mL contains 20 mg of propofol
<b>Other ingredients (inactive ingredients)</b>	Soya oil, Medium-chain triglycerides, Egg lecithin, Glycerol, Sodium oleate, Water for injections
<b>Potential allergens</b>	Soya

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

### What PROPOFOL-LIPURO looks like

PROPOFOL-LIPURO is a milky-white oil in water emulsion for injection or infusion. It contains either propofol 10 mg/mL or 20 mg/mL and is supplied in ampoules, vials or bottles.

Australian registration number:

#### PROPOFOL-LIPURO 1%:

20 mL ampoule AUST R 142906 (pack of 5 ampoules)  
 20 mL vial AUST R 220082 (pack of 10 vials)  
 50 mL bottle AUST R 220083 (pack of 10 bottles)  
 100 mL bottle AUST R 220081 (pack of 10 bottles)

#### PROPOFOL-LIPURO 2%:

50 mL bottle AUST R 220084 (pack of 10 bottles)

### Who distributes PROPOFOL-LIPURO

B. Braun Australia Pty Ltd  
 Level 5, 7-9 Irvine Place  
 Bella Vista NSW 2153  
 Australia

Toll Free Number: 1800 251 705

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