

DIPRIVAN®

Propofol

Consumer Medicine Information

Name of consumer

Address of consumer

What is in this leaflet

This leaflet answers some common questions about DIPRIVAN. It does not contain all the available information.

This leaflet does not replace advice from your anaesthetist, surgeon, doctor or pharmacist.

If you have any questions, or are not sure about anything, ask your doctor or pharmacist.

Keep this information after your operation or hospital stay. You may want to read it again later.

What DIPRIVAN is used for. How it works.

General Anaesthesia

DIPRIVAN is used as a short-acting general anaesthetic that can be given into the blood stream through a needle. It is used in adults, and children aged one month and older. A general anaesthetic is a medicine which produces general anaesthesia. This is the condition of heavy sleep needed during surgery. Short-acting means that a patient goes to sleep quickly, usually within 30 seconds of receiving DIPRIVAN, but then wakes up quickly as it wears off. It can be used for very short operations when only one injection or dose is needed. DIPRIVAN can be used for longer operations if

more is given as repeat doses (maintenance anaesthesia). It can be used to start off an anaesthetic (induction anaesthesia). This means that the anaesthetist may change over to a gas anaesthetic after you have gone to sleep.

Sedation

DIPRIVAN can also be given to adults slowly in low doses if you need to be sedated or sleepy, but do not need the heavy sleep of anaesthesia. Some people require DIPRIVAN for this use during special tests which may be called procedures. After some operations it is useful to keep a patient sedated while they are in the "intensive care" area. Your anaesthetist may need to give you a pain-relieving or relaxing medicine.

Every anaesthetic is different and depends on the particular operation, procedure or medical care you are having. Your anaesthetist and surgeon are trained to look after every need you have while you are asleep or having a procedure done. He or she will decide which medicine to use as and when a need arises.

Before you are given DIPRIVAN

Before you start to use it.

You must tell your doctor if:

1. **You have an allergy to propofol or any of the other ingredients listed at the end of this leaflet.**

2. You have any of these medical conditions:

- Epilepsy
- A very high blood fat level. This warning only applies to very rare conditions, not the more common high blood cholesterol.
- Any other health problems such as problems with your heart, breathing, kidneys or liver or if you have been generally unwell for some time.

3. You are pregnant or breast feeding

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

4. Do not give DIPRIVAN to children younger than one month of age for general anaesthesia.

Do not give DIPRIVAN to children 16 years or younger for sedation.

5. If you are on any other medicine. This is important, especially if you are on any strong pain relievers, heart medication, medicines used to produce calmness or help you sleep or medicines that you buy at the Pharmacy, supermarket or health food shop yourself.

How DIPRIVAN is given

DIPRIVAN comes in a special glass container which may be a vial or a syringe. This will be supplied to your anaesthetist.

DIPRIVAN is given by an injection into a vein, usually in the forearm or the back of the hand. Your anaesthetist may use a fine plastic tube called a cannula. The amount of DIPRIVAN you are given will be decided by your anaesthetist. DIPRIVAN may be given via a syringe driver or by a computer controlled pump called the Diprifusor® under the immediate supervision of the anaesthetist. In longer operations, or if you are having DIPRIVAN to sedate you, the anaesthetist may use an electric pump to control or slow the injection. The dose of DIPRIVAN will be adjusted to keep you at the right depth of sleep or sedation. The dose of DIPRIVAN needed for sedation is less than that needed for anaesthesia.

If you are older, a child, or have some kind of heart trouble, your anaesthetist may be able to use lower doses to get the right depth of sleep or sedation.

While you are receiving DIPRIVAN

Your anaesthetist, surgeon and nursing staff are trained to look after every need that you have while you are asleep or sedated. If you are receiving DIPRIVAN for general anaesthesia the anaesthetist may need to use several different medicines to keep you asleep, pain free, breathing in a healthy way and with good blood pressure.

If you are receiving DIPRIVAN for sedation, other drugs will usually be given at the same time for pain relief. The mix and doses of drugs needs to be chosen by specially-trained doctors and adjusted for each patient according to need.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have been given DIPRIVAN.

People usually wake up quickly after anaesthesia with DIPRIVAN. As with all medicines, unwanted effects sometimes happen. Some of the unwanted effects of DIPRIVAN are the result of sleep being too light or too deep. Your anaesthetist will reduce the dose of DIPRIVAN if your blood pressure is too low, or if you need help breathing. The dose may be increased if you move or wriggle a bit. Other medicines may be needed if your heart rate becomes too slow or irregular.

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

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

- feeling like fainting
- having difficulty breathing
- pain during injection
- elation or euphoria
- headache
- shivering
- feeling sick or vomiting
- cough
- skin rash

These are common side effects of DIPRIVAN.

Tell your doctor or a nurse immediately if you notice any of the following:

- muscle pain
- severe upper stomach pain
- breathlessness

These are all serious side effects of DIPRIVAN. You may need urgent medical attention. Serious side effects are rare.

Do not drive a car or operate machinery. After receiving DIPRIVAN your ability to drive a car or to operate machinery may be affected for some time. Therefore, if you are able to go home soon after your operation do not drive a car or operate machinery. This is important. Ask your doctor when you can return to work involving machinery or heavy equipment.

Disposal

Each new vial or syringe of DIPRIVAN is only for single patient use. The hospital staff looking after you will dispose of any remaining DIPRIVAN appropriately.

Product description

What it looks like:

DIPRIVAN is a milky, white liquid which comes in either a vial or a syringe.

- DIPRIVAN 20 mL vial
- DIPRIVAN 50 mL vial
- DIPRIVAN 100 mL vial
- DIPRIVAN 50 mL syringe

Ingredients:

Active ingredients:

- DIPRIVAN - 10 mg of propofol per 1 mL

Inactive ingredients:

- glycerol
- soya oil
- egg lecithin
- sodium hydroxide
- disodium edetate

Sponsor

AstraZeneca Pty Ltd
Alma Road
North Ryde NSW 2113

Free call number : 1800 805 342

ABN 54 009 682 311

DIPRIVAN is a trademark of the AstraZeneca group of companies.

The information contained in this leaflet was prepared in June 2005.

Australian Registration numbers are:

DIPRIVAN 50 mL syringe - 75562

DIPRIVAN 20 mL vial - 77251[^]

DIPRIVAN 50 mL vial - 75565[^]

DIPRIVAN 100 mL vial - 75564[^]

[^] non-marketed in Australia