

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

**P DIPRIVAN® 1%
Propofol injection 10 mg / mL**

Read this carefully before you start taking **DIPRIVAN® 1%** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **DIPRIVAN® 1%**.

What is DIPRIVAN® 1% used for?

- DIPRIVAN® 1% (propofol) belongs to a group of medicines called general anaesthetics. It is used to induce or maintain anaesthesia.

How does DIPRIVAN® 1% work?

DIPRIVAN® 1% causes you to become unconscious (asleep) while surgical operations or other procedures are being conducted. In adults only, smaller doses can also be used in certain circumstances to sedate you (make you sleepy or make you go to sleep lightly).

The effect of DIPRIVAN® 1% starts rapidly, within approximately 30 seconds. The recovery period from anaesthesia or sedation is also usually rapid.

What are the ingredients in DIPRIVAN® 1%?

Medicinal ingredients: Propofol 10 mg/mL

Non-medicinal ingredients: disodium edetate, egg phosphatide, glycerol, sodium hydroxide, soybean oil and water for injection.

DIPRIVAN® 1% comes in the following dosage forms:

DIPRIVAN® 1% is available as DIPRIVAN® 1% in 20 mL, 50 mL and 100 mL glass vials for single infusion only.

Do not use DIPRIVAN® 1%:

- In children under the age of 18 years for sedation during surgical/diagnostic procedures or in the intensive care unit (ICU).
- In children under the age of 3 years old for anaesthesia.
- If you have ever received DIPRIVAN® 1% before and have experienced an allergic reaction to its use or if you know that you are allergic to any of the ingredients listed in this leaflet (see What are the ingredients in DIPRIVAN® 1%).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take DIPRIVAN® 1%. Talk about any health conditions or problems you may have, including:

- All health problems you have now or have had in the past.
- Other medicines you take, including ones you can buy without a prescription.
- If you have any other health problems such as problems with your:
 - heart,
 - breathing,
 - kidneys or liver

- or if you have been generally unwell for some time.
- If you have ever had an epileptic fit or seizures.
- If you have ever been told that either you have very high fat levels in your blood or your body has problems in breaking down fat adequately.
- If you are pregnant, plan to become pregnant or are breastfeeding.

Other warnings you should know about:

DIPRIVAN® 1% may temporarily interfere with your ability to drive or operate tools or machinery.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with DIPRIVAN® 1%:

- -Some drugs interact with DIPRIVAN® 1%. Tell your doctor about all prescription, over the-counter and natural health products that you are using.
- Usage of such medicines at the same time as DIPRIVAN® 1% may increase the risk of serious side effects.
- Avoid alcohol before and for at least 8 hours after receiving DIPRIVAN® 1%.

How to take DIPRIVAN® 1%:

DIPRIVAN® 1% will be given to you by your anaesthesiologist or intensive care doctor.

Usual dose:

The dose given is decided by the doctor based on the clinical need and your physical condition.

When Receiving DIPRIVAN®1%

DIPRIVAN® 1% will be given to you as an injection into a vein, usually in the back of the hand or in the forearm. Your anaesthesiologist may use a needle. For long operations and for use in intensive care situations, an electric pump may be used to control the rate at which the injection is given.

After Receiving DIPRIVAN®1%

You may feel some pain in the arm into which DIPRIVAN® 1% is given; this is normal.

Your anaesthesiologist or intensive care doctor will closely control the amount of DIPRIVAN® 1% that is given to you. The amount will be adjusted according to how deeply your anaesthesiologist or intensive care doctor wishes you to sleep or be sedated. He/she will also take account of your age and physical fitness and adjust the amount accordingly.

Several different medicines may be needed in order to keep you asleep or sedated, free from pain, breathing in a healthy way and to keep your blood pressure steady. Your anaesthesiologist or intensive care doctor will decide which medicines to use as the need arises.

During prolonged use of DIPRIVAN® 1% for intensive care, certain patients may need to be given zinc (a mineral) supplements.

Overdose:

If you think you have taken too much DIPRIVAN® 1%, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using DIPRIVAN®1%?

These are not all the possible side effects you may feel when taking DIPRIVAN® 1%. If you experience any side effects not listed here, contact your healthcare professional.

DIPRIVAN®1% can cause abnormal blood test results, including high levels of fat in the blood. Your doctor will decide when to perform blood tests and will interpret the results.

| Serious side effects, how often they happen and what to do about them | | | |
|---|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| DURING USE OF DIPRIVAN 1% | | | |
| VERY COMMON A feeling of pain near the injection site | ✓ | | |
| COMMON A fall in blood pressure | | ✓ | |
| A slower heart beat | | ✓ | |
| Changes in your breathing pattern | | ✓ | |
| RARE Some twitching and shaking | | ✓ | |
| Feeling of euphoria (sense of happiness) | | ✓ | |
| VERY RARE Allergic reactions: includes swelling of face, hives, rash and itchiness | | | ✓ |
| Fluid in the lungs: severe shortness of breath, difficulty breathing and wheezing, especially when lying down | | | ✓ |
| UNKNOWN Discolouration of the urine | | ✓ | |
| Breakdown of muscle cells | | | |

| | | | |
|--|---|---|---|
| (rhabdomyolysis): muscle pain, muscle weakness and dark urine | | | ✓ |
| AFTER USE OF DIPRIVAN 1% | | | |
| COMMON Nausea and vomiting | ✓ | | |
| Headache | ✓ | | |
| UNCOMMON Redness or soreness where DIPRIVAN® 1% was given | ✓ | | |
| RARE Some twitching and shaking | | ✓ | |
| Feeling of euphoria (sense of happiness) | | ✓ | |
| VERY RARE Inflammation of the pancreas (pancreatitis): long periods of pain in the stomach and/or intestine area may go around to your back. You may also vomit. | | ✓ | |
| Fluid in the lungs: severe shortness of breath, difficulty breathing and wheezing, especially when lying down | | ✓ | |
| Feeling hot, have increased body temperature or fever, or flushed skin | | ✓ | |
| A feeling of sexual arousal or long- lasting penile erection | | ✓ | |
| Fainting or loss of consciousness, | | ✓ | |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

If you want more information about DIPRIVAN®1%:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website <https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>, the manufacturer's website www.aspenpharma.ca, or by calling 1-844-330-1213.

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