

PART III: CONSUMER INFORMATION

[Fr] DIPRIVAN[®] 1% w/v Propofol injection 10 mg/mL

This leaflet is part III of a three-part “Product Monograph” published when DIPRIVAN was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DIPRIVAN. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

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

WHAT IT DOES:

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

WHEN IT SHOULD NOT BE USED:

- In children under the age of 18 years for sedation during surgical/diagnostic procedures or in the intensive care unit.
- If you have ever received DIPRIVAN 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 THE NONMEDICINAL INGREDIENTS ARE)

WHAT THE MEDICINAL INGREDIENT IS:

Propofol 10 mg/mL.

WHAT THE NONMEDICINAL INGREDIENTS ARE:

DIPRIVAN contains disodium edetate, egg phosphatide, glycerol, sodium hydroxide, soybean oil and water for injection.

WHAT DOSAGE FORMS IT COMES IN:

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

WARNINGS AND PRECAUTIONS

You should talk to your doctor or anesthetist prior to surgery:

- About all health problems you have now or have had in the past.
- About 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 convulsion.
- If you have ever been told that either you have very high fat levels in your blood or your body has problems in metabolising fat adequately.
- If you are pregnant, plan to become pregnant or are breastfeeding.
- If you are planning to drive or operate any tools or machinery on the day of surgery, because DIPRIVAN may temporarily interfere with your reactions and muscular coordination.

INTERACTIONS WITH THIS MEDICATION

Some drugs interact with DIPRIVAN. Tell your doctor about all prescription, over-the-counter and natural health products that you are using (see WARNINGS AND PRECAUTIONS above).

Usage of such medicines at the same time as DIPRIVAN may increase the risk of serious side effects.

PROPER USE OF THIS MEDICATION

HOW DIPRIVAN IS USED:

DIPRIVAN will be given to you by your anaesthetist 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

DIPRIVAN will be given to you as an injection into a vein, usually in the back of the hand or in the forearm. Your anaesthetist may use a needle, or a fine plastic tube called a cannula. 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

You may feel some pain in the arm into which DIPRIVAN is given; this is normal. Your anaesthetist or intensive care doctor will closely control the amount of DIPRIVAN that is given to you. The amount will be adjusted according to how deeply your anaesthetist or intensive care doctor wishes you to be sedated or anaesthetised.

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 anaesthetist or intensive care doctor will decide which medicines to use as the need arises.

Serious adverse effects resulting from an overdose are extremely rare and need special treatment. The doctor is trained and equipped to handle such situations.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, DIPRIVAN can have side effects. **Your anaesthetist or intensive care doctor will care for you if any of the following side effects or any other undesirable events occurs.**

Medicines affect different people in different ways. Just because side effects have occurred in some patients, does not mean that you will get them.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

DURING ANAESTHESIA

More than 10 of every 100 patients (very common) may experience:

- A feeling of pain near the injection site before the injection makes you unconscious

1 to 10 of every 100 patients (common) may experience:

- A fall in blood pressure
- A slower heart beat
- Changes in your breathing pattern

Less than 1 of every 1000 patients (rare) may experience:

- Some twitching and shaking

The majority of the above reactions are mild and transient in nature.

Less than 1 of every 10 000 patients (very rare) may experience:

- Allergic reactions
- Fluid in the lungs

AFTER ANAESTHESIA

1 to 10 of every 100 patients (common) may experience:

- Nausea and vomiting
- Headache

Less than 1 of every 100 patients (uncommon) may experience:

- Redness or soreness where the anaesthetic was given

Less than 1 of every 1000 patients (rare) may experience:

- Some twitching and shaking

Less than 1 of every 10 000 patients (very rare) may experience:

- Inflammation of the pancreas
- Fluid in the lungs
- Increased body temperature
- A feeling of sexual arousal
- Postoperative unconsciousness – recovery without complications has always occurred

DURING INTENSIVE CARE SEDATION (ADULTS ONLY)

1 to 10 of every 100 patients (common) may experience:

- A fall in blood pressure
- A slower heart beat

Less than 1 of every 100 patients (uncommon) may experience:

- Redness or soreness where the anaesthetic was given

Less than 1 of every 1000 patients (rare) may experience:

- Some twitching and shaking

Less than 1 of every 10 000 patients (very rare) may experience:

- Allergic reactions
- Increased body temperature
- Breakdown of muscle cells (rhabdomyolysis) when DIPRIVAN has been given in excess of the maximum recommended dose rate. A causal relationship with DIPRIVAN has not been established.
- Inflammation of the pancreas
- Discolouration of the urine

This is not a complete list of side effects. For any unexpected effects while or after taking DIPRIVAN contact your doctor or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

NOTE: This INFORMATION FOR THE CONSUMER leaflet provides you with the most current information at the time of printing.

The Consumer Information Leaflet plus the full Product Monograph, prepared for health professionals can be found at:

www.astrazeneca.ca,

or by contacting the sponsor, AstraZeneca Canada Inc. at:
Customer Inquiries – 1 (800) 668-6000,
Renseignements – 1 (800) 461-3787.

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