

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

Rx DIPRIVAN® 1%

propofol emulsion

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% is used:

- in adults and children 3 years of age and older during surgery and other medical procedures to make the patient become unconscious (asleep).
- in adults in the Intensive Care Unit (ICU) and in other medical settings to keep patients sedated (a very relaxed state of calm, drowsiness or sleep).

How does DIPRIVAN® 1% work?

DIPRIVAN 1% belong to a group of medicines called general anesthetics. These types of medicines work by causing a loss of feeling and awareness that feels like being in a deep sleep.

What are the ingredients in DIPRIVAN® 1%?

Medicinal ingredients: propofol

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

DIPRIVAN® 1% comes in the following dosage forms:

Emulsion; 10 mg / mL

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).
- 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 propofol or any of the nonmedicinal ingredients (including eggs or egg products and soybeans or soy products) in DIPRIVAN 1% (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,
 - pancreas,
 - thyroid,
 - 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 have diabetes.
- If you are pregnant, plan to become pregnant or are breastfeeding.

Other warnings you should know about:

Driving and using machines: DIPRIVAN® 1% may temporarily interfere with your ability to drive or operate tools or machinery. You should not drive or operate machinery until all the effects of DIPRIVAN 1% have worn off.

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%:

- Midazolam (used to induce sedation (a very relaxed state of calm, drowsiness or sleep) and relieves anxiety and muscle tension).
- Opioid medicines, such as fentanyl (used to treat severe pain).
- Other medicines that have an effect on the nervous system, breathing and blood pressure.
- 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 healthcare professional based on the medical procedure it is being used for 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.

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.

If DIPRIVAN® 1% is used for a long time in intensive care situations, certain patients may need to be given zinc (a mineral) supplements.

After Receiving DIPRIVAN® 1%

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

Overdose:

If you think you, or a person you are caring for, have been given too much DIPRIVAN® 1%, contact a 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 have when taking DIPRIVAN® 1%. If you experience any side effects not listed here, tell your healthcare professional.

Serious side effects 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: swelling of face, hives, rash and itchiness, including anaphylactic shock and anaphylactoid reaction			✓
Fluid in the lungs: severe shortness of breath, difficulty breathing and wheezing, especially when lying down			✓
UNKNOWN Discolouration of the urine		✓	

Serious side effects 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	
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.		✓	

Serious side effects 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	
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, tell 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.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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.aspenpharma.ca, or by calling 1-844-330-1213.

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