

Fresofol 1%

Propofol 1% w/v

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Fresofol 1%. It does not contain all the available information. It does not take the place of talking to your doctor or anaesthetist. All medicines have risks and benefits. Your doctor or anaesthetist has weighed the risks of you being given Fresofol 1% against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or anaesthetist. Keep this leaflet. You may need to read it again.

What is Fresofol 1% used for?

General Anaesthesia

Fresofol 1% contains propofol, which is used as a short-acting general anaesthetic in adults and children aged 3 years or older.

Fresofol 1% is a general anaesthetic agent that puts you in heavy sleep which is needed during surgery. Fresofol 1% is short-acting which means that once you are given Fresofol 1% it will put you to sleep quickly, usually within 30 seconds. You will wake up quickly as the effect wears off.

If you are undergoing surgery, Fresofol 1% can be used to put you to sleep, and then your anaesthetist may give you more Fresofol 1% or he/she may change over to a gas anaesthetic to keep you asleep during surgery.

Sedation

Fresofol 1% can be given to adults and adolescents over 16 years of age in lower doses if they need to be sedated or sleepy, but do not need the heavy sleep of anaesthesia. Fresofol 1% can also be given slowly (by a special pump) if you need to be sedated. This may be necessary during special tests or procedures or after an operation. Your anaesthetist or doctor may need to give you a pain-relieving or relaxing medicine as well.

Ask your doctor or anaesthetist if you have any questions about why this medicine has been prescribed for you. Your doctor or anaesthetist may have prescribed it for another reason.

Fresofol 1% is not addictive.

Fresofol 1% is available only with a doctor's prescription.

Before you are given Fresofol 1%

When you must not be given Fresofol 1%

You must not be given Fresofol 1% if you (or the person you are caring for) are:

- allergic to egg-yolk containing foods, peanut or soy products or any of the other ingredients as listed at the end of this leaflet (including propofol, egg lecithin, glycerol, soya oil and sodium hydroxide). Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash; itching or hives on the skin.

- younger than 3 years of age.
- pregnant or breastfeeding.
- younger than 16 years of age and will be sedated during tests or procedures or will be sedated in the intensive care ward.

Before you use Fresofol 1%

You must also tell your anaesthetist, surgeon or doctor if you (or the person you are caring for):

- have allergies to proteins of eggs, peanuts or soy or any other medicines, food, preservatives or dyes.
- have ever had an epileptic fit or convulsion.
- have other health problems with your heart, breathing, kidneys or liver or you have not been feeling well lately.
- are taking strong pain relievers or heart medications or other medications that has been prescribed by your doctor or bought over the counter from your pharmacy, supermarket or health food shops.
- have a disorder with fat metabolism or a condition of very high fat level in the blood. This is a rare condition which is different from high cholesterol in the blood.

Tell your doctor or anaesthetist if you are pregnant or if you intend to become pregnant or are breast-feeding. Fresofol 1% is not recommended for use during pregnancy or breast-feeding. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor or anaesthetist if you are taking or using any other medicines, including any that you buy without a prescription from

CMI for Fresofol

your pharmacy, supermarket or health food shop.

Some medicines and propofol may interfere with each other. These include:

- strong pain relievers;
- medicines used to produce calmness or to help you to sleep;
- some medicines used to treat anxiety;
- some medicines used to treat epilepsy, eg barbiturates.

Your doctor or anaesthetist may have information on medicines to be careful with or avoid when you are given Fresofol 1%.

How Fresofol 1% is given

Fresofol 1% must only be administered only by a doctor or anaesthetist.

Fresofol 1% is given by injection into a vein, usually in the forearm or the back of the hand. Fresofol 1% can also be given by a computer controlled pump to control or slow the injection to keep you asleep or sedated.

Each vial is used for one dose in one patient only. Any remaining contents must be discarded after each dose.

How much of Fresofol 1% is given

Your doctor or anaesthetist will decide how much Fresofol 1% you are to be given. This will depend on your age and other factors such as your weight and the duration of your procedure. The dose will be adjusted to keep you at the right depth of sleep or sedation.

Overdose

As Fresofol 1% is given to you under the supervision of your doctor or anaesthetist, it is very

unlikely that you will receive too much. Your doctor or anaesthetist has information on how to recognise and treat an overdose.

Otherwise, immediately telephone your doctor or contact the Poisons Information Centre in your country.

Australia: 13 11 26

New Zealand: 0800 764 766.

Ask your doctor or anaesthetist if you have any concerns.

While you are receiving Fresofol 1%

Things to be careful of:

Do not drive a car or operate machinery for some hours after you have been given Fresofol 1%.

As with other anaesthetics, Fresofol 1% may cause impairment of skilled tasks, such as driving or operating machinery, for some time after you have been given it.

Ask your doctor when you can return to work involving driving, or operating machinery or heavy equipment.

Side Effects

This medicine helps provide anaesthesia or sedation for most people, but it may have unwanted side effects in a few people.

Tell your doctor or anaesthetist as soon as possible if you do not feel well after you have been given Fresofol 1%.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

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

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

- Pain, heat or tingling at the injection site;
- Flushing of the skin;
- Dizziness;
- Nausea or vomiting, cough, headache, shivering, restlessness or mood changes when you are waking up from the anaesthetic;
- Hiccups or stopping breathing very briefly.

The above list includes the more common side effects of your medicine. They are usually mild and short lived.

Tell your doctor as soon as possible if you notice any of the following:

- Slow, fast or irregular heart beat;
- Convulsions (fitting);
- Signs of an allergic reaction, such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin;
- Severe pain in the upper stomach;
- Temporary paralysis or weakness of the muscles.

The above list includes serious side effects.

Some of the side effects of Fresofol 1% may occur whilst you are asleep or sedated. Your doctor or anaesthetist is trained to manage these reactions in the unlikely event that they occur.

Tell your doctor or anaesthetist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Storage Conditions

Fresofol 1% will be stored in the pharmacy or on the ward.

CMI for Fresofol

Fresofol 1% is kept in a cool dry place where the temperature stays below 25°C.

Any unused Fresofol 1% from the opened vial will be discarded.

Date of information

This information leaflet was prepared in 18 August 2010

Product Description

What it looks like

Fresofol 1% is a milky, white liquid. It is available in 20 mL in ampoules, 50 mL and 100 mL in vials.

Ingredients

Active ingredients:

- Propofol 10 mg/mL

Inactive ingredients:

- Soya oil
- Glycerol
- Egg lecithin
- Oleic acid
- Sodium hydroxide
- Water for Injections

Australian registration numbers:

Fresofol 1% 20 mL: AUSTR 98270

Fresofol 1% 50 mL: AUSTR 98271

Fresofol 1% 100 mL: AUSTR 98275

Further Information

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

Sponsor

Fresenius Kabi Australia Pty
Limited
964 Pacific Highway
Pymble NSW 2073
Australia
Telephone: (02) 9391 5555

Fresenius Kabi New Zealand
Limited
60 Pavilion Drive
Airport Oaks, Auckland 2022
New Zealand
Freecall: 0800 144 892