

Fresofol[®] 1% MCT/LCT

Propofol 1% w/v

Consumer Medicine Information

What is in this leaflet

This leaflet contains some common questions about Fresofol 1% MCT/LCT.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risk of you taking this medicine against the benefits they expect it will have for you.

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

What is Fresofol 1% MCT/LCT used for

It is a short-acting sleep inducing medicinal product used to start and sustain a general anaesthesia.

It is used to induce sleep or lower your level of consciousness (as a sedative) during intensive care or during diagnostic or surgical procedures.

Before you are given Fresofol 1% MCT/LCT

When you must not be given Fresofol 1% MCT/LCT

Do not use Fresofol 1% MCT/LCT:

- if you are allergic (hypersensitive) to Propofol or any of the other ingredients of Fresofol 1% MCT/LCT

- if you are allergic (hypersensitive) to soya or peanut

Take special care with Fresofol 1% MCT/LCT if:

- you have a disorder in which your body does not handle fat properly
- you have any other health problems which require caution in the use of fat emulsions
- you are very overweight
- your blood volume is too low (hypovolaemia)
- you are very weak or have heart, circulatory, kidney or liver problems
- you have high pressure within the skull and low blood pressure in the arteries
- you have problems with your breathing
- you have epilepsy
- you are undergoing some procedures where spontaneous movements are particularly, undesirable.

Please tell your doctor if you have one of these diseases or conditions.

Do not give Fresofol 1% MCT/LCT in children of one month of age or younger as a general anaesthetic.

Do not give Fresofol 1% MCT/LCT in children 16 years or younger as a sedative.

It will not be used when you are receiving electroconvulsive therapy (electric shock treatment in cases

of severe long lasting epileptic attacks).

Taking or using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may depress your breathing or your blood circulation when combined with Propofol or prolong the effect of Propofol:

Painkillers, benzodiazepine tranquillisers, narcotic gases, some local anaesthetics, fentanyl, other medicinal products usually given before operations.

On the other hand, the sedative effect of some of these medicinal products may become stronger.

When given together with Propofol, certain medicines used for muscle relaxation (suxamethonium) or as antidote (neostigmine) may depress heart function.

Occurrence of a specific organic changes in the brain (leucoencephalopathy) has been reported in patients having received fat emulsions such as Fresofol 1% MCT/LCT together with cyclosporin (a medicine used to suppress rejection reactions after organ transplantation and to suppress overreactions of the immune system).

Make sure that your doctor knows if you are taking any of these medicinal products.

Using Fresofol 1% MCT/LCT with food and drink

Alcohol and Propofol make the sedative effects of each other stronger. Therefore you should not drink alcohol just before or just after you have Fresofol 1% MCT/LCT.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Fresofol 1% MCT/LCT should not be used during pregnancy.

If you are breast-feeding your child, you should stop nursing and discard breast milk for 24 hours after you have received Fresofol 1% MCT/LCT. Studies in breast-feeding women showed that Propofol is excreted in small amounts into the milk.

Driving and using machines

You should not drive or operate machinery for a while after you have had an injection or infusion of Fresofol 1% MCT/LCT. Your doctor will tell you how long you must wait before you drive or use machinery again.

Important information about some of the ingredients of Fresofol 1% MCT/LCT

This medicinal product contains less than 1 mmol (23 mg) sodium in 100 mL, that is, it is essentially 'sodium free'.

How to use Fresofol 1% MCT/LCT

Fresofol 1% MCT/LCT will only be given by anaesthetists or by specially trained doctors in an intensive care unit.

Dosage

The dose you are given will vary depending on your age, body

weight and physical condition. The doctor will give the correct dose to start and to sustain anaesthesia or to achieve the required level of sedation, by carefully watching your responses and vital signs (pulse, blood pressure, breathing, etc). The doctor will also observe limits of the time of application, if necessary.

Fresofol 1% MCT/LCT will usually be given by injection when used to induce general anaesthesia and by continuous infusion (a slower, longer injection) when used to maintain general anaesthesia. It may be given as an infusion either diluted or undiluted. When used as a sedative it will usually be given by infusion.

Fresofol 1% MCT/LCT will only be given for a maximum of 7 days.

Method of administration

You will receive Fresofol 1% MCT/LCT by intravenous injection or infusion, that is, through a needle or small tube placed in one of your veins.

Because Fresofol 1% MCT/LCT does not contain preservatives, an infusion from one vial of Fresofol 1% MCT/LCT will not last longer than 12 hours. An infusion from one container of diluted Fresofol 1% MCT/LCT will not last longer than 6 hours.

Your circulation and breathing will be constantly monitored while you are being given the injection or infusion.

Overdose

If you received more Fresofol 1% MCT/LCT than you should

It is unlikely that this occurs because the doses you receive are very carefully controlled.

If you accidentally got an overdose, this could lead to depression of heart function, circulation and breathing. In this case your doctor

will employ necessary treatment immediately.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia) or 0800 764 766 (New Zealand).

Possible Side Effects

Like all medicines, Fresofol 1% MCT/LCT emulsion for injection or infusion can cause side effects, although not everybody gets them.

The meaning of the terms to describe the frequency of side effects in the following text is:

- very common (more than 1 out of 10 patients)
- common (more than 1 out of 100 patients and less than 1 out of 10 patients)
- uncommon (more than 1 out of 1,000 patients and less than 1 out of 100 patients)
- rare (more than 1 out of 10,000 patients and less than 1 out of 1,000 patients)
- very rare (less than 1 out of 10,000 patients, also including isolated cases)

A doctor must be called immediately if the following happen

Uncommon:

- A strong drop of blood pressure. This may need special treatment and may include infusion of fluid and suitable medicines to bring your the blood pressure back to normal.

Rare:

- Allergic reactions including swelling of the face, tongue or throat, wheezing breath, flushing and falling blood pressure

- Convulsions like in epilepsy
- Irregular heartbeat or too slow heartbeat. To bring your heartbeat back to normal, suitable medicines may have to be given.

Very rare:

- Convulsive fits occurring a few hours to several days after use of Propofol.
- In isolated cases, convulsions have been observed in epileptic patients after administration of Propofol.
- There have been cases of unconsciousness occurring after operations. You will therefore be carefully observed during the waking-up time.
- Swelling of lungs (lung oedema) after administration of Propofol (isolated cases)
- Inflammation of the pancreas occurred after administration of Propofol. It remains doubtful, however, whether Propofol could have caused this.
- There have been reports of isolated cases of severe adverse reactions presenting as a combination of the following symptoms: breakdown of muscle tissue, accumulation of acidic (sour) substances in the blood, abnormally high blood potassium level, high blood fat levels, and heart failure. This has been called the "Propofol infusion syndrome". Some of the affected patients eventually died. These effects have only been seen in patients in intensive care with doses higher than 4 mg of Propofol per kg body weight per hour.
- Severe tissue reactions after injection into tissue surrounding the vein.

When Fresofol 1% MCT/LCT is given together with lidocaine, which may be given for pain reduction, the following side effects may

occur: giddiness, vomiting, sleepiness, convulsions, changes in heart beat and shock.

Other Side effects are:

Very common:

- Pain at the injection site occurring during the first injection. The pain may be reduced by injecting lidocaine (a local anaesthetic) at the same time.

Common:

- Spontaneous movements and muscle twitching during the start of general anaesthesia
- Mild or moderate drop of blood pressure
- Fast breathing or short interruption of breathing, coughing
- Hiccups during induction of anaesthesia
- Hot flushes during start of anaesthesia

Uncommon:

- Involuntary muscle contractions and other uncontrolled movements.
- Coughing during general anaesthesia.

Rare:

- Abnormally good mood or loss of sexual control during the time of recovery.
- Headache, giddiness, shivering and feeling cold during the time of recovery.
- Coughing during the recovery period.
- Sickness or vomiting during the time of recovery.
- Abnormal colour of urine after longer lasting administration of Propofol.
- Cases of fever after an operation.
- Blood clots in veins or inflammation of veins.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet,

please tell your doctor or pharmacist.

Storage

Keep out of the reach and sight of children.

Do not use Fresofol 1% MCT/LCT after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Do not freeze. Fresofol 1% MCT/LCT must be used immediately after opening the ampoule, vial or pre-filled syringe.

Do not use Fresofol 1% MCT/LCT if two separate layers can be seen after shaking the product.

Product Description

What Fresofol 1% MCT/LCT looks like:

It is a milky-white oil-in-water emulsion available in:-

- a 20 mL glass ampoule
- a 20 mL, 50 mL and 100 mL glass vial
- a 50 mL plastic pre-filled syringe

Ingredients:

Active ingredient: propofol
1 ampoule with 20 mL contains 200 mg propofol.

1 vial with 20 mL contains 200 mg propofol.

1 vial with 50 mL contains 500 mg propofol.

1 pre-filled syringe with 50 mL contains 500 mg propofol.

1 vial with 100 mL contains 1000 mg propofol.

Inactive ingredients:

Soya oil, medium-chain triglycerides, egg lecithin, glycerol,

CMI for Fresofol 1% MCT/LCT

sodium hydroxide, oleic acid, Water
for Injections

Australian registration number:

Fresofol 1% MCT/LCT 20 mL
ampoules: AUST R 193608

Fresofol 1% MCT/LCT 20 mL vials:
AUST R 193607

Fresofol 1% MCT/LCT 50 mL vials:
AUST R 193609

Fresofol 1% MCT/LCT 50 mL pre-
filled syringe: AUST R 204474

Fresofol 1% MCT/LCT 100 mL
vials: AUST R 193610

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Sponsor

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