

FRESOFOL[®] 1% MCT/LCT

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given FRESOFOL 1% MCT/LCT?

FRESOFOL 1% MCT/LCT contains the active ingredient propofol. FRESOFOL 1% MCT/LCT 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.

For more information, see Section [1. Why am I being given FRESOFOL 1% MCT/LCT?](#) in the full CMI.

2. What should I know before I am given FRESOFOL 1% MCT/LCT?

Do not use if you have ever had an allergic reaction to FRESOFOL 1% MCT/LCT or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I am given FRESOFOL 1% MCT/LCT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FRESOFOL 1% MCT/LCT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How is FRESOFOL 1% MCT/LCT given?

Your doctor will decide how much FRESOFOL 1% MCT/LCT you should receive and for how long you should receive it.

More instructions can be found in Section [4. How is FRESOFOL 1% MCT/LCT given?](#) in the full CMI.

5. What should I know after being given FRESOFOL 1% MCT/LCT?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you have received FRESOFOL 1% MCT/LCT.
Things you should not do	<ul style="list-style-type: none">Do not take any other medicines whether they require a prescription or not without first telling your doctor.
Driving or using machines	<ul style="list-style-type: none">You should not drive or operate machinery for a while after you have had an injection or infusion of Fresofo 1% MCT/LCT. Your doctor will tell you how long you must wait before you drive or use machinery again.
Looking after your medicine	<ul style="list-style-type: none">FRESOFOL 1% MCT/LCT is stored by hospital staff in the pharmacy or in the ward.This medicine is kept below 25 °C and do not freeze.

For more information, see Section [5. What should I know after being given FRESOFOL 1% MCT/LCT?](#) in the full CMI.

6. Are there any side effects?

• **Less serious side effects:** Giddiness, vomiting, sleepiness, pain at the injection site, mild to moderate drop in blood pressure, fast breathing or short interruption of breathing, coughing, hiccups, involuntary muscle contractions, abnormally good mood, loss of sexual control, headache, shivering, abnormal colour of urine and fever.

Speak to your doctor if you have any of these less serious side effects and they worry you.

• **Serious side effects:** strong drop in blood pressure, allergic reactions including swelling of the face, tongue or throat, wheezing breath, flushing and falling blood pressure, convulsive fits, irregular heartbeat or too slow heartbeat, unconsciousness, swelling of lungs, changes in heartbeat and shock.

Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FRESOFOL 1% MCT/LCT

Active ingredient: Propofol

Consumer Medicine Information (CMI)

This leaflet provides important information about using FRESOFOL 1% MCT/LCT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FRESOFOL 1% MCT/LCT.**

Where to find information in this leaflet:

1. [Why am I being given FRESOFOL 1% MCT/LCT?](#)
2. [What should I know before I am given FRESOFOL 1% MCT/LCT?](#)
3. [What if I am taking other medicines?](#)
4. [How is FRESOFOL 1% MCT/LCT given?](#)
5. [What should I know while receiving FRESOFOL 1% MCT/LCT?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given FRESOFOL 1% MCT/LCT?

FRESOFOL 1% MCT/LCT contains the active ingredient propofol. FRESOFOL 1% MCT/LCT is a short-acting sleep-inducing medicinal product used to start and sustain a general anaesthesia.

FRESOFOL 1% MCT/LCT is used to induce sleep or lower your level of consciousness (as a sedative) during intensive care or during diagnostic or surgical procedures.

Your doctor may have prescribed FRESOFOL 1% MCT/LCT for another reason. Ask your doctor if you have any question about why FRESOFOL 1% MCT/LCT has been prescribed for you.

FRESOFOL 1% MCT/LCT is not addictive.

2. What should I know before I am given FRESOFOL 1% MCT/LCT?

Warnings

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
- you are allergic (hypersensitive) to soya or peanut
- you are receiving electroconvulsive therapy (electric shock treatment in cases of severe long lasting epileptic attacks)

Check with your doctor 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. FRESOFOL 1% MCT/LCT is not recommended for use while you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. FRESOFOL 1% MCT/LCT is not recommended for use while you are breastfeeding. 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with FRESOFOL 1% MCT/LCT and affect how it works.

- Some medicines may depress your breathing or your blood circulation when combined with Propofol or prolong the effect of Propofol such as 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).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect FRESOFOL 1% MCT/LCT.

4. How is FRESOFOL 1% MCT/LCT given?

How much is given

- Your doctor will decide how much FRESOFOL 1% MCT/LCT you will receive and for how long you will receive it; this depends on your condition and other factors such as your age and weight.
- 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).
- FRESOFOL 1% MCT/LCT will only be given for a maximum of 7 days

How FRESOFOL 1% MCT/LCT is given to you

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

If you are given too much FRESOFOL 1% MCT/LCT

- Since FRESOFOL 1% MCT/LCT is given to you in hospital by a doctor or a nurse, it is very unlikely that you will be given too large a dose.
- However, if you think that you have received too much FRESOFOL 1% MCT/LCT and you experience severe side effects, tell your doctor immediately.
- Symptoms of an overdose may include the side effects listed below in the 'Side effects' section but are usually of a more severe nature. Ask your doctor or pharmacist if you have any concerns.

5. What should I know while receiving FRESOFOL 1% MCT/LCT?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are receiving FRESOFOL 1% MCT/LCT.

Things you should not do

Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FRESOFOL 1% MCT/LCT affects you.

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.

Looking after your medicine

FRESOFOL 1% MCT/LCT is stored by hospital staff in the pharmacy or in the ward.

This medicine is kept below 25 °C and do not freeze.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, hospital staff will take it to the pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less Serious side effects	What to do
Nervous system-related: <ul style="list-style-type: none">• Giddiness• Sleepiness• Headache• fever	Speak to your doctor if you have any of these less serious side effects and they worry you.
Blood vessel system-related: <ul style="list-style-type: none">• Mild to moderate drop in blood pressure	

<p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> Vomiting <p>Respiratory system-related:</p> <ul style="list-style-type: none"> Fast breathing or short interruption of breathing Coughing <p>Injection site-related:</p> <ul style="list-style-type: none"> Pain at the site of injection <p>Muscular system-related:</p> <ul style="list-style-type: none"> Involuntary muscle contractions <p>Other:</p> <ul style="list-style-type: none"> Hiccups Abnormally good mood Loss of sexual control Shivering Abnormal colour of urine 	
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Serious side effects

Serious side effects	What to do
<p>Heart-related:</p> <ul style="list-style-type: none"> Irregular heartbeat Too slow heartbeat Changes in heartbeat <p>Blood vessel system-related:</p> <ul style="list-style-type: none"> Strong drop in blood pressure Flushing <p>Nervous system-related:</p> <ul style="list-style-type: none"> Convulsive fits Unconsciousness Shock <p>Respiratory system-related:</p> <ul style="list-style-type: none"> Wheezing breath Swelling of lungs <p>Allergic reaction-related:</p> <ul style="list-style-type: none"> Swelling of face, tongue or throat 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects after being discharged from the hospital.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems. By reporting

side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What FRESOFOL 1% MCT/LCT contains

Active ingredient (main ingredient)	Propofol
Other ingredients (inactive ingredients)	Soya oil Medium-chain triglycerides Egg lecithin Glycerol, Sodium hydroxide Oleic acid Water for Injections

Do not take this medicine if you are allergic to any of these ingredients.

What FRESOFOL 1% MCT/LCT looks like

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

AUST R	Strength	Container	Pack size
193608	200mg/20mL	Glass ampoule	5's,10's
193607	200mg/20mL	Glass vial	5's
193609	500mg/50mL	Glass vial	10's
193610	1000mg/100mL	Glass vial	10's
204474	500mg/50mL	Pre-filled syringe	1

Who distributes FRESOFOL 1% MCT/LCT

Fresenius Kabi Australia Pty Limited
Level 2, 2 Woodland Way
Mount Kuring-gai NSW 2080
Australia
Telephone: (02) 9391 5555

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