Patient Information Leaflet for PROPOFOL MCT/LCT 2 % FRESENIUS

SCHEDULING STATUS: : S5

PROPOFOL MCT/LCT 2 % FRESENIUS

Emulsion for injection or infusion

Propofol

Contains sugar (as glycerol 22,5 mg/mL)

Contains soya-bean oil, refined 50 mg

Read all of this leaflet carefully before you are given PROPOFOL MCT/LCT 2 % FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet:

1. What PROPOFOL MCT/LCT 2 % FRESENIUS is and what it is used for

PROPOFOL MCT/LCT 2 % FRESENIUS belongs to a group of medicines called “general anaesthetics”. General anaesthetics are used to cause unconsciousness (sleep) so that surgical operations or other procedures can be performed.

PROPOFOL MCT/LCT 2 % FRESENIUS is used to:

- induce and maintain general anaesthesia,
- sedate adults receiving artificial respiration in the intensive care unit (ICU).

2. What you need to know before you are given PROPOFOL MCT/LCT 2 % FRESENIUS

PROPOFOL MCT/LCT 2 % FRESENIUS should not be administered:

- if you are hypersensitive (allergic) to propofol or any of the other ingredients of PROPOFOL MCT/LCT 2 % FRESENIUS (listed in section 6),
- if you are allergic to soya or peanuts,
- in children less than 3 years of age,
- for sedation of children of all ages with croup or epiglottitis (inflammation of the glottis) receiving intensive care,
- in patients of 16 years of age or younger for sedation in intensive care.

Warnings and precautions

Special care should be taken with PROPOFOL MCT/LCT 2 % FRESENIUS.

Tell your doctor, pharmacist or healthcare provider before being given the injection:

- if you have advanced heart failure, or heart disease

- if you have lung disease, severe breathing problems (respiratory failure)
- if you have kidney disease
- if you have liver disease
- if your body has lost lots of water (you are hypovolaemic)
- if you have seizures (epilepsy)
- if you have altered levels of fat in the blood. If you are receiving total parenteral nutrition (feeding through a vein), the levels of fat in your blood must be monitored.
- if you are receiving electroconvulsive therapy (ECT, a treatment for psychiatric problems)
- if you have a raised pressure inside the skull (raised intracranial pressure). In combination with low blood pressure the amount of blood reaching the brain may be decreased.
- if you have been told that you have mitochondrial disease (a genetic disorder).

PROPOFOL MCT/LCT 2 % FRESENIUS may increase the risk of:

- epileptic seizures
- a nervous reflex that slows the heart rate (vagotonia, bradycardia)
- changes in the blood flow to the organs of the body (haemodynamic effects on the cardiovascular system) if you are overweight and receive high doses of PROPOFOL MCT/LCT 2 % FRESENIUS.

Occasionally, after anaesthesia, there may be a period of unconsciousness associated with stiffness of the muscles. This requires observation by the medical staff, but no other treatment. It will resolve spontaneously.

The injection of PROPOFOL MCT/LCT 2 % FRESENIUS can be painful. Your doctor may use a local anaesthetic to reduce the pain.

You will not be allowed to leave the hospital until you are fully awake. If you are able to go home shortly after receiving PROPOFOL MCT/LCT 2 % FRESENIUS, you should not go home unaccompanied.

PROPOFOL MCT/LCT 2 % FRESENIUS may interfere with daily activities for up to 24 hours. You should not make any legal/contractual decisions for 24 hours after receiving anaesthesia/sedation.

In general, PROPOFOL MCT/LCT 2 % FRESENIUS should be given with caution to elderly or weak patients.

Children and adolescents

The use of PROPOFOL MCT/LCT 2 % FRESENIUS is not recommended in children younger than 3 years of age (see “PROPOFOL MCT/LCT 2 % FRESENIUS should not be administered”).

PROPOFOL MCT/LCT 2 % FRESENIUS must not be given to children and adolescents younger than 16 years of age for sedation in the intensive care unit, since its safety has not been demonstrated in this patient group for this indication.

Other medicines and PROPOFOL MCT/LCT 2 % FRESENIUS

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor if you are taking/receiving any of the following medicines:

- premedications (your anaesthetist will know which medicines can be influenced by PROPOFOL MCT/LCT 2 % FRESENIUS)
- other anaesthetics, including general, regional, local and inhalational anaesthetics. (lower doses of PROPOFOL MCT/LCT 2 % FRESENIUS may be required)
- painkillers (analgesics)
- strong painkillers (fentanyl or opioids)
- benzodiazepines (medicines used to treat anxiety)
- suxamethonium, atracurium, mivacurium (muscle relaxants)
- rifampicin (an antibiotic used in tuberculosis (TB))
- alcohol containing medicines or beverages
- neostigmine (medicine used to treat a disease called myasthenia gravis)
- ciclosporin (medicine used to prevent transplant rejections)
- valproate (medicine used to treat epilepsy or mental disorders).

Receiving PROPOFOL MCT/LCT 2 % FRESENIUS with food and drink

After you have been given PROPOFOL MCT/LCT 2 % FRESENIUS, you should not eat, drink or consume alcohol until fully recovered.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor or other healthcare provider for advice before receiving PROPOFOL MCT/LCT 2 % FRESENIUS.

PROPOFOL MCT/LCT 2 % FRESENIUS should not be given to pregnant women.

You should stop breastfeeding and discard any breastmilk for 24 hours after receiving PROPOFOL MCT/LCT 2 % FRESENIUS.

Driving and using machinery

After having PROPOFOL MCT/LCT 2 % FRESENIUS you may still feel sleepy for some time. Do not drive, operate machinery, or work in dangerous situations.

If you are able to go home shortly after receiving PROPOFOL MCT/LCT 2 % FRESENIUS, do not go home alone.

Ask your doctor when you can start doing these activities again and when you can go back to work.

PROPOFOL MCT/LCT 2 % FRESENIUS contains soya-bean oil and sodium

PROPOFOL MCT/LCT 2 % FRESENIUS contains soya-bean oil. This can cause severe hypersensitivity (allergic) reactions. If you are allergic to peanuts, soya or egg protein, do not use this product. Tell your doctor if you know that you are allergic to soya-bean oil or peanuts.

PROPOFOL MCT/LCT 2 % FRESENIUS contains sodium (less than 1 mmol (23 mg) sodium per 100 mL, i.e., essentially “sodium-free”).

3. How PROPOFOL MCT/LCT 2 % FRESENIUS will be given to you

You will not be expected to give yourself PROPOFOL MCT/LCT 2 % FRESENIUS. It will only be given to you in hospitals or suitable therapy units by a person who is qualified to do so.

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 (such as pulse, blood pressure, breathing, etc.).

You may need several different medicines to keep you asleep or sleepy, free from pain, breathing in a healthy way and to keep your blood pressure steady. The doctor will decide which medicines you need and when you need them.

Children and adolescents over three years of age:

The use of PROPOFOL MCT/LCT 2 % FRESENIUS is not recommended in children younger than 3 years of age.

The dose should be adjusted according to age and/or body weight.

PROPOFOL MCT/LCT 2 % FRESENIUS must not be given to children and adolescents younger than 16 years of age for sedation in the intensive care unit, since its safety has not been demonstrated in this patient group for this indication.

Method of administration:

PROPOFOL MCT/LCT 2 % FRESENIUS is for intravenous use, usually on the back of your hand or in the forearm. Your anaesthetist may use a needle or cannula (a fine plastic tube).

PROPOFOL MCT/LCT 2 % FRESENIUS will be injected into a vein either manually or by an electric pump. An electric pump may be used to give the injection for long operations and for use in intensive care.

When used for sedation, PROPOFOL MCT/LCT 2 % FRESENIUS must not be administered for more than 72 hours.

If you received more PROPOFOL MCT/LCT 2 % FRESENIUS than you should

Since a healthcare provider will administer PROPOFOL MCT/LCT 2 % FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

However, different people need different doses and if you do receive too much for you, your anaesthetist may need to take measures to make sure your heart and breathing are adequately supported. This is why anaesthetics are only administered by doctors trained in anaesthesia or in the care of patients in intensive care.

If you have any further questions on the use of this medicine, ask your anaesthetist or intensive care doctor.

If you missed a dose of PROPOFOL MCT/LCT 2 % FRESENIUS

Since a healthcare provider will administer PROPOFOL MCT/LCT 2 % FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

PROPOFOL MCT/LCT 2 % FRESENIUS can have side effects.

Not all side effects reported for PROPOFOL MCT/LCT 2 % FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PROPOFOL MCT/LCT 2 % FRESENIUS, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor immediately in order to stop the administration of PROPOFOL MCT/LCT 2 % FRESENIUS:

- Serious allergic reaction which causes swelling of the lips, face and throat, difficulty in breathing, swollen and reddened skin, hot flushes
- Build up of fluid in the lungs which can make you feel breathless (may also happen when you wake up)
- Inflamed pancreas (pancreatitis) which causes severe stomach pain
- Kidney failure (decreased urine output, swelling, shortness of breath).

These are all very serious side effects. If you have them, you may have had a serious reaction to PROPOFOL MCT/LCT 2 % FRESENIUS. You may need urgent medical attention or further hospitalisation.

Tell your doctor or healthcare provider if you notice any of the following:

<u>Frequent side effects:</u>

- Headache

- Slow or fast heartbeat
- Low blood pressure
- Changes in your breathing pattern, hiccups
- Cough
- Feeling sick (nausea), being sick (vomiting)
- A feeling of pain at the site of the injection (while the injection is being given before you fall asleep).

Less frequent side effects:

- Twitching and shaking of your body, or fits (may also happen when you wake up)
- Dizziness, shivering, chills and sensations of cold
- Being unconscious after the operation (when this has happened, the patients have recovered without problems)
- Swelling and redness or blood clots at the vein along the injection site
- Unusual colour of urine (may also happen when you wake up)
- Fever following surgery.

Frequence not known (frequency cannot be estimated from the available data):

- Feeling euphoric (intense excitement)
- Feeling sexually aroused (inappropriate sexual behaviour)
- Medicine abuse, dependance, mostly by healthcare professionals
- Involuntary movements

- Irregular heart beat, changes in ECG
- Respiratory depression (you may experience shallow breathing and shortness of breath)
- Increase in liver size (your doctor will conduct blood tests to determine this)
- Breakdown of muscle cells (rhabdomyolysis) - you may notice muscle weakness, pain and dark red or brown urine
- Increase in acidity of your blood, high potassium and fat levels in your blood, heart failure (your doctor will conduct blood tests to determine this)
- Prolonged erection
- Pain, swelling, following accidental injection into the tissue around the vein.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PROPOFOL MCT/LCT 2 % FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address:

safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store PROPOFOL MCT/LCT 2 % FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. For single use. Any unused emulsion must be discarded. Do not throw away any medicines via wastewater or household waste.

Do not use this medicine after the expiry date which is stated on the vial and the outer packaging after EXP. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What PROPOFOL MCT/LCT 2 % FRESENIUS contains

The active substance is propofol.

Each mL of the emulsion contains 20 mg propofol.

Each 50 mL vial contains 1 000 mg propofol.

The other ingredients are soya-bean oil, medium-chain triglycerides, purified egg phosphatides, glycerol, oleic acid, sodium hydroxide (for pH-adjustment), water for injections.

What PROPOFOL MCT/LCT 2 % FRESENIUS looks like and contents of the pack

PROPOFOL MCT/LCT 2 % FRESENIUS is a white, homogeneous oil-in-water emulsion.

Colourless glass vial(s) (type II) of 50 mL with a bromobutyl rubber closure.

Packs containing 1, 10 or 16 glass vial(s) with 50 mL emulsion.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Fresenius Kabi South Africa (Pty) Ltd

Stand 7, Growthpoint Business Park

162 Tonetti Street

Halfway House Extension 7

Midrand, 1685

Gauteng, South Africa

Telephone number: +27 (0)11 545 0000

This leaflet was last revised in

30 January 2025

Registration number

41/2.1/1124

Access to the corresponding Professional Information

The professional information will be printed and packaged with the product.