PATIENT INFORMATION LEAFLET

Scheduling status: S5

PROPOFOL MCT/LCT 1 % (20 mL) FRESENIUS

PROPOFOL MCT/LCT 1 % (50 mL) FRESENIUS

PROPOFOL MCT/LCT 1 % (100 mL) FRESENIUS

Emulsion for injection or infusion

Propofol

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

Contains soya-bean oil, refined 50 mg/mL

Read all of this leaflet carefully before you are given PROPOFOL MCT/LCT 1 % FRESENIUS.

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

What is in this leaflet

1. What PROPOFOL MCT/LCT 1 % FRESENIUS is and what it is used for
2. What you need to know before you are given PROPOFOL MCT/LCT 1 % FRESENIUS
3. How PROPOFOL MCT/LCT 1 % FRESENIUS will be given to you
4. Possible side effects
5. How to store PROPOFOL MCT/LCT 1 % FRESENIUS
6. Contents of the pack and other information

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

PROPOFOL MCT/LCT 1 % FRESENIUS is a short-acting intravenous general anaesthetic. General anaesthetics are used to cause unconsciousness (sleep) so that surgical operations or other procedures can be performed. They can also be used to sedate you (so that you are sleepy but not completely asleep).

PROPOFOL MCT/LCT 1 % FRESENIUS is used to:

- induce and maintain general anaesthesia
- sedate you when receiving artificial respiration in an Intensive Care Unit (ICU) for a period of up to 72 hours
- sedate you during surgical and diagnostic procedures.

2. What you need to know before you are given PROPOFOL MCT/LCT 1 % FRESENIUS

PROPOFOL MCT/LCT 1 % FRESENIUS should not be administered:

- if you are hypersensitive (allergic) to propofol or to any of the other ingredients of PROPOFOL MCT/LCT 1 % FRESENIUS (listed in section 6)
- if you have an allergy to soya or peanuts
- in children under the age of 3 years
- for sedation of children of all ages with croup or epiglottitis (inflammation of the glottis) receiving intensive care
- for sedation of patients less than 16 years of age in the intensive care unit.

Warnings and precautions

Special care should be taken with PROPOFOL MCT/LCT 1 % FRESENIUS

Tell your doctor 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 you have mitochondrial disease (a genetic disorder).

PROPOFOL MCT/LCT 1 % FRESENIUS may increase the risk of:

- epileptic seizures (“fits”)
- a nervous reflex that slows the heart rate (vagotonia, bradycardia).

Very 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 1 % 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 1 % FRESENIUS, you should not go home unaccompanied.

PROPOFOL MCT/LCT 1 % 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 1 % FRESENIUS should be given with caution to elderly or weak patients.

Children and adolescents

The use of PROPOFOL MCT/LCT 1 % FRESENIUS is not recommended in children less than 3 years of age (see “PROPOFOL MCT/LCT 1 % FRESENIUS should not be administered”).

PROPOFOL MCT/LCT 1 % 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 1 % FRESENIUS

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

Make sure your doctor knows if you are also taking/receiving any of the following medicines:

- Anticholinergic medicines (medicines used to treat e.g. painful cramps of organs, asthma or Parkinson's disease)

- Benzodiazepines (medicines used to treat anxiety)
- Strong painkillers (fentanyl or opioids)
- Painkillers (analgesics)
- Premedication (your anaesthetist will know which medicines can be influenced by PROPOFOL MCT/LCT 1 % FRESENIUS)
- Other anaesthetics, including general, regional, local and inhalational anaesthetics. (Lower doses of PROPOFOL MCT/LCT 1 % FRESENIUS may be required.)
- Alcohol containing medicines or beverages
- Suxamethonium, atracurium, mivacurium (muscle relaxant)
- Neostigmine (medicine used to treat a disease called myasthenia gravis)
- Ciclosporin (medicine used to prevent transplant rejections)
- Rifampicin (medicine used to treat tuberculosis)
- Valproate (medicine used to treat epilepsy or mental disorders).

Receiving PROPOFOL MCT/LCT 1 % FRESENIUS with food and drink

After you have been given PROPOFOL MCT/LCT 1 % FRESENIUS, you should not eat, drink or consume alcohol until fully recovered.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving PROPOFOL MCT/LCT 1 % FRESENIUS.

PROPOFOL MCT/LCT 1 % FRESENIUS should not be given to pregnant women.

You should stop breastfeeding and discard any breastmilk for 24 hours after receiving PROPOFOL MCT/LCT 1 % FRESENIUS.

Driving and using machinery

After having PROPOFOL MCT/LCT 1 % FRESENIUS you may still feel sleepy for some time. You should not perform skilled tasks, such as driving and operating machines, for 24 hours after general anaesthesia.

If you are able to go home shortly after receiving PROPOFOL MCT/LCT 1 % 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 1 % FRESENIUS contains soya-bean oil and sodium

Soya-bean oil can cause severe allergic reactions (see “PROPOFOL MCT/LCT 1 % FRESENIUS should not be administered”). Tell your doctor if you know that you have allergic reactions to soya-bean oil or peanuts.

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

3. How PROPOFOL MCT/LCT 1 % FRESENIUS will be given to you

You will not be expected to give yourself PROPOFOL MCT/LCT 1 % FRESENIUS. It will be given to you 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 3 years of age:

The use of PROPOFOL MCT/LCT 1 % 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 1 % 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 1 % 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 1 % FRESENIUS will be injected into a vein either manually or by electric pumps. 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 1 % FRESENIUS should not be administered for more than 72 hours.

For induction of anaesthesia, PROPOFOL MCT/LCT 1 % FRESENIUS is not recommended for children under the age of 3 years.

For maintenance of anaesthesia PROPOFOL MCT/LCT 1 % FRESENIUS is not recommended for children under the age of 3 years.

Administration of PROPOFOL MCT/LCT 1 % FRESENIUS via a TCI (target-controlled infusion) system is restricted to induction and maintenance of general anaesthesia in adults. It is not recommended for use in children or in the intensive care unit (ICU) sedation or sedation for surgical and diagnostic procedures.

If you received more PROPOFOL MCT/LCT 1 % FRESENIUS than you should

Since a healthcare provider will administer PROPOFOL MCT/LCT 1 % 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 1 % FRESENIUS

Since a healthcare provider will administer PROPOFOL MCT/LCT 1 % FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

PROPOFOL MCT/LCT 1 % FRESENIUS can have side effects.

Not all side effects reported for PROPOFOL MCT/LCT 1 % FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving PROPOFOL MCT/LCT 1 % FRESENIUS, please consult your healthcare provider for advice.

If any of the following happens, tell your doctor immediately in order to stop administrating PROPOFOL MCT/LCT 1 % 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 feeling 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 1 % FRESENIUS. You may need urgent medical attention and further hospitalisation.

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

<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.

Frequency not known:

- Feeling euphoric (intense excitement)
- Feeling sexually aroused (inappropriate sexual behaviour)
- Medicine abuse, dependence, 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 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 application beside 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 1 % 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 1 % FRESENIUS

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not freeze.

Single dose vial. Unused portions should be disposed of by a healthcare provider.

Do not use after the expiry date stated on the carton and ampoule/vial.

6. Contents of the pack and other information

What PROPOFOL MCT/LCT 1 % FRESENIUS contains

The active substance is propofol.

1 mL emulsion contains 10 mg propofol.

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

What PROPOFOL MCT/LCT 1 % FRESENIUS looks like and contents of the pack

PROPOFOL MCT/LCT 1 % FRESENIUS is a white, homogeneous emulsion. Do not use if two layers can be seen after shaking the emulsion.

Packs containing 5 glass ampoules or 5 and 10 glass vials with 20 mL emulsion for intravenous injection. Packs containing 1, 10 or 15 glass vials with 50- or 100-mL emulsion for intravenous infusion. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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PROPOFOL MCT/LCT 1 % (50 mL) FRESENIUS: 41/2.1/1122

PROPOFOL MCT/LCT 1% (100 mL) FRESENIUS: 41/2.1/1123

Access to the corresponding Professional Information

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