Proposed Patient Information Leaflet for MILSIA 1 % & 2 %

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

MILSIA 1 % 20 mL emulsion for injection/infusion

MILSIA 1 % 50 mL emulsion for injection/infusion

MILSIA 1 % 100 mL emulsion for injection/infusion

MILSIA 2 % emulsion for injection/infusion

Propofol

Sugar-free.

Read all of this leaflet carefully before MILSIA is administered to you.

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

What is in this leaflet:

1. What MILSIA is and what it is used for
2. What you need to know before MILSIA is adminstered
3. How MILSIA is administered
4. Possible side effects
5. How to store MILSIA

6. Contents of the pack and other information

1. What MILSIA is and what it is used for

MILSIA is used as an anaesthetic, or as a sedative during diagnostic and surgical procedures or during ventilation in the intensive care unit.

In adults and children over the age of 3 years MILSIA is used to:

- Help put you to sleep before and operation or other procedure.
- Keep you asleep during an operation or other procedure.

In adult patients MILSIA is also used to:

- Sedate you during diagnostic and surgical procedures, alone or in combination with local or regional anaesthesia.
- Sedate you when receiving artificial respiration in an intensive care unit (ICU).

2. What you need to know before MILSIA is administered to you

MILSIA should not be administered to you:

- If you are hypersensitive (allergic) to propofol or any of the other ingredients of MILSIA (listed in section 6).
- If you are allergic to peanuts, soya protein or egg.
- If you are a child under the age of 3.
- If you are a child under the age of 18, receiving MILSIA for sedation, and you and also suffering from a barking cough (croup) or inflammation of the tissue protecting the windpipe (epiglottitis).

Warnings and precautions:

Tell your doctor before receiving MILSIA:

- If you have very high levels of fat in your blood or if you have been told your body has problems using fat.

- If you have any other health problems, such as breathing, heart, kidney or liver problems.
- If you are using other medicines that make breathing difficult.
- If you are elderly or weak.
- If you have a history of epilepsy.
- If you are dehydrated (when your body has lost lots of water).
- If you have mitochondrial disease.
- If you are receiving electroconvulsive treatment, as MILSIA should not be recommended.

Children and adolescents:

MILSIA should not be administered to children under the age of three.

MILSIA may not be be used for sedation in children under the age of 18. Also see section “MILSIA should not be administered to you”.

Other medicines and MILSIA:

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

Tell your doctor if you are taking:

- Medicines containing opioids (used to treat pain).
- Benzodiazepines (group of medicines used for anxiety, as muscle relaxants, sedatives or anaesthetics, or to support treatment of alcohol withdrawal symptoms).
- Local anaesthetics (medicines that causes absence of pain sensation during surgery).
- Fentanyl (used to help prevent pain after an operation).
- Ciclosporin (used after an organ transplant to prevent organ rejection).
- Rifampicin (to treat tuberculosis [TB]).
- Valproate (to treat fits [seizures] or migraine).

MILSIA with food, drink and alcohol:

You should not drink alcohol just before you are receiving, or just after you have received MILSIA.

Pregnancy and breastfeeding:

You should not be given MILSIA if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or health care provider for advice before being administered MILSIA.

Driving and using machines:

You may feel dizzy and sleepy for some time after you have received MILSIA.

You should not drive or operate machinery after you have had an injection or infusion of MILSIA.

Your doctor will tell you how long you must wait before you can drive or operate machinery again.

MILSIA contains sodium chloride:

MILSIA contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially ‘sodium-free’.

MILSIA contains egg and soya:

If you are allergic to egg, peanut or soya, do not use MILSIA.

3. How MILSIA will be administered

You will not be expected to give yourself MILSIA

MILSIA will only be given by an anaesthetist or by a specially trained doctor in an intensive care unit.

MILSIA is for intravenous use only. Your doctor will decide on the suitable dose based on your age, body weight and physical condition.

If you have the impression that the effect of MILSIA is too strong or too weak, tell your doctor or pharmacist.

If you receive more MILSIA than you should:

Since a health care provider will administer MILSIA, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive MILSIA:

Since a health care provider will administer MILSIA, it is unlikely that the dose will be missed.

4. Possible side effects

MILSIA can have side effects.

Not all side effects reported for MILSIA are included in this leaflet.

Should your general health worsen or if you experience any untoward effects after been given MILSIA, please consult your health care provider for advice.

Side effects that can happen during anaesthesia:

The following side effects can happen during anaesthesia (while the injection is being given to you or when you are sleepy or asleep). Your doctor will be looking out for these. If they happen, your doctor will give you appropriate treatment.

- Allergic reactions: swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing and breathing, redness of the skin.
- Low blood pressure or high blood pressure.
- Twitching and shaking of your body, or a fit (this may also happen when you wake up), spasm of the muscles causing backward arching of the head, neck, and spine.

- Abnormally rapid, slow or irregular heartbeat.
- Build-up of fluid in the lungs which can make you very breathless (this may also happen when you wake up), temporary stopping of breathing.
- Changes in your breathing pattern.
- Unusual colour of urine (this may also happen when you wake up).

Side effects that can happen after anaesthesia:

The following side effects can happen after anaesthesia (when you are waking up or after you have woken up).

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- “Withdrawal symptoms”, these include unusual behaviour, sweating, shaking and feeling anxious.
- Swelling and redness along the vein or blood clots.
- Blood clotting, inflammation of the walls of the vein.
- Involuntary movements, convulsions and epileptic type movements.
- Changes in the way you heart beats, for example, if you notice it beating faster, or sometimes beating slower than normal.
- Heart failure (a condition in which the heart doesn't pump blood as well as it should), sometimes with fatal outcome. Symptoms include shortness of breath, fatigue, swollen legs and rapid heartbeat.
- Inflamed pancreas (pancreatitis) which causes severe stomach pain.
- Too much acid in your blood. This may make you breathe more quickly. You may also experience nausea and vomiting.

- Enlarged liver with symptoms such as yellowing of the skin or eyes (jaundice), fatigue, nausea and weight loss.
- Breakdown of muscle cells, which can lead to kidney damage. Symptoms include dark, reddish urine, a decreased amount of urin, weakness and muscle aches.
- Kidney failure, with symptoms such as a reduced amount of urine, swelling of your legs, ankles and feet, unexplained shortness of breath, nausea and confusion.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Flushing of the skin.
- Headaches.
- Hiccups or coughing.
- A feeling of pain, redness and / or swelling at the site of the injection.

Less frequent side effects:

- Increased amount of potassium in your blood.
- Euphoric mood.
- Shivering or sensations of feeling cold.
- Being unconscious after the operation.
- Dizziness.
- Nausea, vomiting, stomach cramps.
- Tissue damage.
- Darkening of the skin around the site of injection.
- Feeling sexually aroused.
- Fever.

- Abnormal ECG (a test performed to check with problems with your heart).

Side effects of unknown frequency:

- High blood levels of a type of fat called lipids.
- Muscle pain, weakness, fever, rapid heart rate.

If any of these side effects persists or worsens or 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 or pharmacist. You can also report side effects to SAHPRA via the "**Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MILSIA.

5. How to store MILSIA

- Store at or below 25 °C.
- Do not freeze.
- Shake well before use.
- Use immediately after opening the vial. Any unused emulsion must be thrown away at the end of administration.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MILSIA contains:

The active substance is propofol.

MILSIA 1 % 20 mL: Each vial contains 10 mg/mL propofol.

MILSIA 1 % 50 mL: Each vial contains 10 mg/mL propofol.

MILSIA 1 % 100 mL: Each bottle contains 10 mg/mL propofol.

MILSIA 2 %: Each vial contains 20 mg/mL propofol.

The other ingredients are:

Egg lecithin, glycerol, medium chain triglycerides, refined soybean oil, sodium hydroxide, sodium oleate and water for injection.

What MILSIA looks like and contents of the pack:

A white milky emulsion, practically free from extraneous particulate contamination and large oil droplets.

MILSIA is presented in clear colourless glass 20 mL, 50 mL) or bottle (100 mL) with a grey bromobutyl rubber stopper crimped with a silver coloured aluminium cap and light blue polypropylene flip-off cap. The vials / bottles are placed in a carton with a package insert and patient information
leaflet.

MILSIA is available in the following pack sizes:

MILSIA 1 % 20 mL: Carton containing 5 vials of 20 mL of emulsion for injection or infusion.

MILSIA 1 % 50 mL: Carton containing 1 vial of 50 mL emulsion for injection or infusion.

MILSIA 1 % 100 mL: Carton containing 1 bottle of 100 mL emulsion for injection or infusion.

MILSIA 2 %: Carton containing 1 vial of 50 mL emulsion for injection or infusion.

Holder of certificate of registration and manufacturer:

Biotech Laboratories (Pty) Ltd

Ground floor, Block K West, Central Park

400 16th road, Randjespark, Midrand 1685

South Africa

Tel. no.: 011 848 3050

This leaflet was last revised:

06 April 2021 - SAHPRA approved 03 August 2021

Registration numbers:

MILSIA 1 % 20 mL: A45/2.1/0701

MILSIA 1 % 50 mL: A45/2.1/0702

MILSIA 1 % 100 mL: A45/2.1/0703

MILSIA 2 %: A45/2.1/0704

Date of registration:

30 September 2016