

APPROVED PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****LIDOCAINE HCl 10 % (AMPOULES) FRESENIUS solution for injection****Lidocaine (lignocaine) hydrochloride****Sugar free****Read all of this leaflet carefully before you receive LIDOCAINE HCl FRESENIUS**

- 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 LIDOCAINE HCl FRESENIUS is and what it is used for
2. What you need to know before you receive LIDOCAINE HCl FRESENIUS
3. How to receive LIDOCAINE HCl FRESENIUS
4. Possible side effects
5. How to store LIDOCAINE HCl FRESENIUS
6. Contents of the pack and other information

1. What LIDOCAINE HCl FRESENIUS is and what it is used for

LIDOCAINE HCl FRESENIUS contains lidocaine (lignocaine), which belongs to a group of medicines called cardiac suppressants. Lidocaine (lignocaine) helps to treat heart rhythm disorders.

LIDOCAINE HCl FRESENIUS can be used to treat heartbeat disturbances during a heart operation, during a heart attack, or after digoxin (heart medicine) overdose.

2. What you need to know before you receive LIDOCAINE HCl FRESENIUS

LIDOCAINE HCl FRESENIUS should not be given to you if you:

- Are hypersensitive (allergic) to lidocaine (lignocaine), local anaesthetics or any of the other ingredients of LIDOCAINE HCl FRESENIUS (listed in section 6 of this leaflet).
- Have porphyria (inherited blood disorder that can cause nerve or skin problems).
- Suffer from hypovolaemia (decrease in blood volume resulting from loss of blood, plasma or plasma fluid).
- Have heart rhythm disorders where the heart beats too slow, such as heart block or bradycardia.
- Suffer from a condition called cardiac decompensation, where your heart is not able to maintain efficient circulation.

Warnings and precautions:

Talk to your doctor before receiving LIDOCAINE HCl FRESENIUS if you:

- Have liver disease.
- Have severe kidney disease.
- Suffer from epilepsy (seizures/fits).
- Have heart problems (such as heart failure) or circulation disorders.
- Have severe breathing difficulties.
- Suffer from myasthenia gravis (neuromuscular disease that causes muscle weakness).

Your doctor will monitor your heart by means of an electrocardiogram (ECG) while you receive LIDOCAINE HCl FRESENIUS.

Other medicines and LIDOCAINE HCl FRESENIUS:

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 any of the following medicines:

- Medicines to treat some heart conditions (e.g. kinidine, disopyramide, amiodarone, bretylium, sotalol, dofetilide, metoprolol and nadolol, propranolol).
- Medicines for a stomach ulcer (e.g. cimetidine).
- Medicines for epilepsy (e.g. phenytoin), infections (e.g. erythromycin), depression (e.g. fluvoxamine) or glaucoma (e.g. acetazolamide).
- Medicines for oral contraception (birth control pills) or oral hormone replacement therapy (HRT).
- Medicines used as muscle relaxants during general anaesthesia (e.g. suxamethonium or cisatracurium).
- Medicines used to treat high blood pressure (e.g., loop diuretics or thiazides).

LIDOCAINE HCl FRESENIUS with food and drink:

There are no known interactions between LIDOCAINE HCl FRESENIUS, food and drink.

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, pharmacist or other health care provider for advice before receiving LIDOCAINE HCl FRESENIUS.

The safe use of LIDOCAINE HCl FRESENIUS during pregnancy has not established.

LIDOCAINE HCl FRESENIUS is excreted into breast milk, and you should use it with caution if you are breastfeeding.

Driving and using machines:

LIDOCAINE HCl FRESENIUS may cause side effects such as blurred or double vision, light-headedness, drowsiness or dizziness. Do not drive a car or operate machinery, until you know how LIDOCAINE HCl FRESENIUS will affect you.

3. How to receive LIDOCAINE HCl FRESENIUS

Do not share any medicines prescribed for you with any other person.

You will not be expected to give yourself LIDOCAINE HCl FRESENIUS. It will be given to you by a doctor or a person who is qualified to do so.

LIDOCAINE HCl FRESENIUS will be injected into your muscle or into your vein.

Your doctor will tell you how long your treatment with LIDOCAINE HCl FRESENIUS will last. If you have the impression that the effect of LIDOCAINE HCl FRESENIUS is too strong or too weak, tell your doctor or pharmacist.

If you receive more LIDOCAINE HCl FRESENIUS than you should:

Since a health care provider will administer LIDOCAINE HCl FRESENIUS he/she will control the dosage. However, in the event of overdose, your doctor will manage the overdose.

If you forget to receive LIDOCAINE HCl FRESENIUS:

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

4. Possible side effects

LIDOCAINE HCl FRESENIUS can have side effects.

Not all side effects reported for LIDOCAINE HCl FRESENIUS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using LIDOCAINE HCl FRESENIUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using LIDOCAINE HCl FRESENIUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to LIDOCAINE HCl FRESENIUS. You may need urgent medical attention or hospitalisation.

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

- Irregular heartbeat.
- Problems with the electrical system of your heart and reduced function of your heart.
- A sudden loss of blood flow, due to heart or vessel factors and a very slow heart rate, which may lead to a heart attack.
- You experience a loss of consciousness.
- Fits (seizures), twitching or tremors.
- Breathing difficulties or you stopped breathing for a period.

- Blood disorder, in which too little oxygen is delivered to your cells. Symptoms may include shortness of breath, headache, nausea, rapid heart rate, fatigue, confusion and loss of consciousness.

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

Tell your doctor if you notice any of the following:

- Nausea and vomiting.
- Dizziness, light-headedness, drowsiness.
- A feeling of apprehension, nervousness, confusion or being unable to distinguish between reality and your imagination.
- Headache.
- Sensations of heat, cold or numbness.
- Pins and needles.
- Blurred or double vision.
- Uncontrolled movement of the eyes.
- Ringing in the ears.
- Temporary pain or discomfort in the buttocks or legs.
- Low blood pressure.

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 LIDOCAINE HCl FRESENIUS.

5. How to store LIDOCAINE HCl FRESENIUS

- Store at or below 25 °C.
- 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 LIDOCAINE HCl FRESENIUS contains:

The active ingredient is lidocaine (lignocaine) hydrochloride.

Each ampoule contains 500 mg/5 ml (10 %) lidocaine (lignocaine) hydrochloride anhydrous as lidocaine (lignocaine) hydrochloride monohydrate.

The other ingredients are sodium hydroxide (for pH-adjustment) and water for injection.

What LIDOCAINE HCl FRESENIUS looks like and contents of the pack:

A clear solution in clear glass ampoules.

5 ml clear Type 1 glass OPC ampoules, packed into a PVC blister tray and outer carton.

Pack size: 10 ampoules per outer carton.

Holder of certificate of registration and manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

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Access to the corresponding Professional Information

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