

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LIDOCAINE HCl 2 % 5 ml (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) hydrochloride, which belongs to a group of medicines called local anaesthetics (it numbs a particular area of the body, to prevent you from feeling pain). It also has antidysrhythmic properties, i.e. it acts on heartbeat disturbances.

LIDOCAINE HCl FRESENIUS can be used:

- To treat heartbeat disturbances during a heart operation, during a heart attack, or after digoxin (heart medicine) overdose.
- To stop pain being felt during medical procedures in the area of the body where it is injected.

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

LIDOCAINE HCl FRESENIUS should not be administered 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).
- Suffer from hypovolaemia (decrease in blood volume resulting from loss of blood, plasma, or plasma fluid).
- Have any heart disorders or suffer from low blood pressure (hypotension).
- Have heart rhythm disorders where the heart beats too slow or irregularly, such as heart block or bradycardia.
- Suffer from a condition called cardiac decompensation, where your heart is not able to maintain efficient circulation.
- Have porphyria (inherited blood disorder that can cause nerve or skin problems).

Warnings and precautions

Tell your doctor or health care provider before receiving LIDOCAINE HCl FRESENIUS if you:

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

- Are in shock.
- Have a blood disorder or an imbalance in the constituents of your blood.
- If you have inflammation or infection in the area to be injected.

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

Take special care with LIDOCAINE HCl FRESENIUS:

- Tell your doctor immediately if you begin to experience light-headedness, numbness of your tongue or a ringing in your ears, while receiving LIDOCAINE HCl FRESENIUS (see section 4).

Other medicines and LIDOCAINE HCl FRESENIUS

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

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

- Medicines to regulate the rhythm of your heart (e.g., amiodarone and mexiletine).
- Medicines used as muscle relaxants during general anaesthesia (e.g., suxamethonium).
- Medicines for a stomach ulcer (e.g., cimetidine).
- Medicines used to treat high blood pressure or angina (e.g., propranolol, verapamil).
- Antiviral medicines used to treat infections caused by viruses, such as the human immunodeficiency virus (HIV) (e.g., amprenavir, atazanavir, darunavir and lopinavir).
- Medicines to treat certain psychiatric conditions, such as mental illnesses (e.g., pimozide, sertindole, olanzapine, quetiapine, zotepine).
- Medicines to treat nausea and vomiting (e.g., tropisetron, dolasetron).
- Antibiotics used to treat infections (e.g., quinupristin, dalfopristin).

- Diuretic medicines (water tablets) (e.g., hydrochlorothiazide).
- Medicines for epilepsy (e.g., phenytoin), infections (e.g., erythromycin), depression (e.g., fluvoxamine) or glaucoma (e.g., acetazolamide, timolol).
- Medicines for oral contraception (birth control pills) or oral hormone replacement therapy (HRT).
- Opioid medicine used for pain relief (e.g., fentanyl).

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 early pregnancy has not been 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.

LIDOCAINE HCl FRESENIUS contains sodium chloride:

LIDOCAINE HCl FRESENIUS contains less than 1 mmol sodium (23 mg) sodium per ampoule, that is to say LIDOCAINE HCl FRESENIUS is essentially sodium-free.

2. How to receive LIDOCAINE HCl FRESENIUS

Do not share 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 decide the correct dosage for you and how and when LIDOCAINE HCl FRESENIUS should be given.

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 overdosage, your doctor will manage the overdose.

If a dose of LIDOCAINE HCl FRESENIUS is missed:

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

3. 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 receiving LIDOCAINE HCl FRESENIUS, please consult your health care provider for advice.

If any of the following happens, stop receiving 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:

- Light-headedness, numbness of your tongue or ringing in the ears, which you may experience immediately upon receiving LIDOCAINE HCl FRESENIUS.
- You experience a loss of consciousness or confusion.
- Fits (seizures), twitching or tremors.
- Breathing difficulties (coughing, wheezing, tightness in the chest, shortness of breath), or you stopped breathing for a period.
- Pain or numbness in the back or lower legs, difficulty in walking.
- Problems with controlling your bladder or bowels.
- 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.

- Slowing and stopping of your heart, or changes in the rhythm of your heart, such as an irregular heartbeat.

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

Tell your doctor if you notice any of the following:

Frequency unknown

- Nausea and vomiting.
- Dizziness, light-headedness, drowsiness, a feeling of nervousness.
- A sensation of pins and needles felt in the arms, legs, hands or feet.
- Blurred or double vision.
- Ringing in the ears, becoming more sensitive to everyday sounds.
- Low blood pressure.
- Skin rash and itching.

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 “**6.04 Adverse Drug Reactions & Quality Problem 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 LIDOCAINE HCl FRESENIUS.

Health care providers are asked to report any suspected adverse drug reactions to the 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.

4. How to store LIDOCAINE HCl FRESENIUS.

Store all medicines out of reach of children.

- Store at or below 30 °C.
- 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).

5. Contents of the pack and other information

What LIDOCAINE HCl FRESENIUS contains

- The active substance is lidocaine (lignocaine) hydrochloride.
Each 5 ml ampoule contains 100 mg (2 %) lidocaine (lignocaine) hydrochloride anhydrous (as monohydrate).
- The other ingredients are water for injection, sodium hydroxide (for pH-adjustment) and sodium chloride.

What LIDOCAINE HCl FRESENIUS looks like and contents of the pack

A clear solution in clear 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

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