

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LIDOCAINE HCl 1 % (VIALS) FRESENIUS solution for injection

LIDOCAINE HCl 2 % (VIALS) FRESENIUS solution for injection

Lidocaine (lignocaine) hydrochloride

Sugar free

Read all of this leaflet carefully before you receive LIDOCAINE HCl 1 % AND 2 % (VIALS) 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 1 % AND 2 % (VIALS) FRESENIUS** is and what it is used for
 2. What you need to know before you are given **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**
 3. How to receive **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**
 4. Possible side effects
 5. How to store **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**
 6. Contents of the pack and other information
-
1. What **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS** is and what it is used for

LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS is a local anaesthetic. It numbs the area of the body where it is administered.

2. What you need to know before you are given LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS should not be administered to you

Do not receive LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS:

- if you are hypertensive (allergic) to lidocaine (lignocaine) or any of the other ingredients of **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS** (see section 6)
- if you are dehydrated or suffer from heart disorders (such as heart block or conduction disorders)
- if you suffer from a state of decreased volume of circulating blood (hypovolaemia)
- if you suffer from myasthenia gravis (loss of muscle function and weakness)
- if you suffer from porphyria (a disorder of the blood. Tell your doctor if you have any blood disorders).

Warnings and precautions

Special care should be taken with LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS:

- if you are using heart medication or have heart, lung or breathing problems
- if you have kidney or liver disease
- if you are using a diuretic
- if you suffer from epilepsy or have fits
- if you are in severe shock
- if you 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.

Other medicines and LIDOCAINE HCl 1 % AND 2 % (VIALS) 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 before receiving **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**:

- amiodarone, mexiletine (used to regulate the rhythm of your heart)
- some medicines that relax the skeletal muscles, e.g., suxamethonium
- propranolol (for high blood pressure or other heart problems)
- cimetidine (for stomach ulcer or heart burn)
- anti-viral medicines that used to treat infections caused by viruses (e.g., HIV), such as amprenavir, atazanavir, darunavir, lopinavir
- medicines used to treat certain psychiatric conditions (e.g., pimozide, sertindole, olanzapine, quetiapine, zotepine)
- dolasetron, tropisetrol (used to prevent or treat nausea and vomiting)
- verapamil (used for angina (chest pain) and high blood pressure)
- timolol (used to treat glaucoma)
- quinupristinm, dalfopristin and erythromycin (antibiotics)
- acetazolamide (used to reduce pressure within the eye)
- diuretics (water tablets)
- fluvoxamine (used to treat depression)
- medicines to control fits or epilepsy, e.g., phenytoin
- opioids – strong pain-relieving medicines (e.g., fentanyl)
- oral contraceptives or oral HRT (hormone replacement therapy)

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 health care provider for advice before receiving **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**.

Do not receive **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS** if you are pregnant or breastfeeding.

Driving and using machines

It is not always possible to predict to what extent **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS** may interfere with your daily activities. You should not engage in the above activities until you know how **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS** affects you. **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS** may affect your ability to drive or operate machinery. Ask your doctor about when it would be safe to drive or operate machines. You should not drive or use machinery if you are affected by the administration of **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**.

3. How to receive LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS

You will not be expected to give yourself **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**. It will be administered by a person who is qualified to do so.

Dosage:

Your doctor will decide what the correct dose is and for how long you will be receiving **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**.

Method of administration:

LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS may be administered by injection into a muscle (intramuscularly).

If you have received more LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS than you should:

Since a healthcare professional will administer **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**, he/she will control the dosage. However, in the event of overdose your doctor

will manage the overdosage.

Missed LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS doses

Since a health care provider will administer **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**, it is unlikely that the dose will be missed.

4. Possible side effects

LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS can have side effects.

Not all side effects reported for **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**, please consult your doctor, pharmacist, or other health care provider for advice.

If any of the following happens, stop receiving **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, 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 allergic reaction to **LIDOCAINE HCl 1 % AND 2 % (VIALS) 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:

- Pale, grey or blue coloured skin
- Fits or convulsions

- Collapse
- Unconsciousness
- Difficulty breathing
- Yellowing of your skin and eyes (also called jaundice).

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

Tell your doctor if you notice any of the following:

- Dizziness or light-headedness, drowsiness, shaking or tremors, numbness of the tongue and mouth area
- Yawning and restlessness
- Excitement and nervousness
- Pain or numbness in the back or lower legs
- Difficulty in walking
- Problems with controlling your bladder or bowels
- Pins and needles
- Blurred or double vision
- Ringing of the ears
- You are more sensitive to everyday sounds
- Sweating
- Low blood pressure. This might make you feel dizzy or light-headed
- Irregular heartbeats and heart failure
- Nausea (feeling sick) and vomiting (being sick)
- Listlessness (lassitude) and loss of memory

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 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 **LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS**.

Health care providers are asked to report any suspected adverse reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicines regulatory authority in the country where the product is marketed.

5. How LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS is stored

Store all medicines out of reach of children.

LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS will be stored in the pharmacy or in the hospital wards.

Store at or below 30 °C.

Unused portions of the injection should be discarded.

6. Contents of the pack and other information

What LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS contains

- The active substance is lidocaine (lignocaine) hydrochloride.

LIDOCAINE HCl 1 % (VIALS) FRESENIUS: Each 1 ml contains lidocaine (lignocaine) hydrochloride monohydrate equivalent to 10 mg lidocaine (lignocaine) hydrochloride anhydrous.

LIDOCAINE HCl 2 % (VIALS) FRESENIUS: Each 1 ml contains lidocaine (lignocaine) hydrochloride monohydrate equivalent to 20 mg lidocaine (lignocaine) hydrochloride anhydrous.

- The other ingredients are sodium chloride, sodium hydroxide, water for injection, 0,1 % *m/v* methyl hydroxybenzoate as preservative.

What LIDOCAINE HCl 1 % AND 2 % (VIALS) FRESENIUS looks like and contents of the pack

LIDOCAINE HCl 1 % (VIALS) FRESENIUS is a clear, colourless solution in 5 or 20 ml clear glass vials (Type 1) sealed with chlorobutyl rubber stoppers with green aluminium caps.

LIDOCAINE HCl 2 % (VIALS) FRESENIUS is a clear, colourless solution in a 20 ml clear glass vials (Type 1) sealed with chlorobutyl rubber stoppers with gold aluminium caps.

Pack size: 10 vials packed in polystyrene containers.

Holder of Certificate of Registration

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

041 403 1600

This leaflet was last revised in

07 July 2023.

Registration numbers

LIDOCAINE HCl 1 % (VIALS) FRESENIUS: G2781 (Act 101/1965)

LIDOCAINE HCl 2 % (VIALS) FRESENIUS G2782 (Act 101/1965)

Access to the corresponding Professional Information

To be confirmed.