

1.3.2. PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

XYLOCAINE 10 mg/0,1 ml Pump Spray

Lidocaine

Contains alcohol: Ethanol 23,136 % *m/v*

Contains sweetener: Saccharin 0,15 mg

Sugar free

Read all of this leaflet carefully before XYLOCAINE 10 mg/0,1 ml 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 healthcare provider.

What is in this leaflet

1. What XYLOCAINE 10 mg/0,1 ml is and what it is used for
2. What you need to know before XYLOCAINE 10 mg/0,1 ml is administered to you
3. How XYLOCAINE 10 mg/0,1 ml will be administered to you
4. Possible side effects
5. How to store XYLOCAINE 10 mg/0,1 ml
6. Contents of the pack and other information

1. What XYLOCAINE 10 mg/0,1 ml is and what it is used for

XYLOCAINE 10 mg/0,1 ml contains the active substance lidocaine.

XYLOCAINE 10 mg/0,1 ml belongs to a group of medicines called local anaesthetics. It works by causing a temporary loss of sensation in the area where it is applied.

XYLOCAINE 10 mg/0,1 ml may be used:

- To produce temporary loss of sensation in a part of the body before certain types of examination are performed by your doctor, e.g. a bronchial examination.
- To help relieve pain associated with minor surgical procedures in the throat, oral and nasal cavity.
- To help relieve pain during puncture of the maxillary sinus (the cavity of the upper jaw).
- In obstetrics: to help relieve pain during the final stages of delivery, before surgical incision into and suturing of the perineum.
- In dentistry: to help relieve pain and/or discomfort, e.g. prior to injection.

2. What you need to know before XYLOCAINE 10 mg/0,1 ml is administered to you

XYLOCAINE 10 mg/0,1 ml should not be administered:

- If you are hypersensitive (allergic) to lidocaine or any of the other ingredients of XYLOCAINE 10 mg/0,1 ml (listed in section 6) or to any local anaesthetics.
- To neonates and infants.

Warnings and precautions

Tell your doctor or healthcare provider before being given XYLOCAINE 10 mg/0,1 ml:

- if you suffer from epilepsy,

- if you have any heart problems such as hypovolaemia (a condition in which the liquid portion of the blood is too low), heart block, decreased heart conduction, congestive heart failure, shock, bradycardia (slow heart rate) or respiratory depression,
- if you have problems with your liver,
- if you have severe problems with your kidney,
- XYLOCAINE 10 mg/0,1 ml should not be used on the cuffs of the plastic tubes used to help you breathe (endotracheal tubes) as the active ingredient may damage the plastic,
- be careful when XYLOCAINE 10 mg/0,1 ml is used in the mouth or throat since numbness in these areas may interfere with swallowing,
- numbness of the tongue or gums may also increase the danger of injury due to biting,
- if you suffer from an inherited disorder of blood pigment metabolism (porphyria),
- avoid using XYLOCAINE 10 mg/0,1 ml on large areas of your skin or for prolonged periods of time,
- avoid using too much or using XYLOCAINE 10 mg/0,1 ml too soon after you already received a dose as you may experience serious side effects,
- XYLOCAINE 10 mg/0,1 ml has a high absorption rate in the lungs therefore applying it to this area may result in toxic symptoms such as convulsions,
- XYLOCAINE 10 mg/0,1 ml should be used with caution if you have a wound or damaged mucosa (lining of the skin) at the application site as the wound may increase the amount of XYLOCAINE 10 mg/0,1 ml absorbed in your system,
- if you are paralysed, the absorption of XYLOCAINE 10 mg/0,1 ml in your blood may be increased when under general anaesthesia,
- doses should be decreased in elderly and debilitated patients.

Children

Doses should be decreased in children.

Other medicines and XYLOCAINE 10 mg/0,1 ml

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

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

- medicines used to treat irregular heart activity (antidysrhythmics) such as amiodarone, mexiletine or tocainide or beta-blockers. Usage of such medicines at the same time may increase the risk of toxic effects described in the section “If you have been given more XYLOCAINE 10 mg/0,1 ml than you should”.
- medicines used to treat stomach ulcers and indigestion (cimetidine).

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 healthcare provider for advice before this medicine is administered to you.

Driving and using machines

It is not always possible to predict to what extent XYLOCAINE 10 mg/0,1 ml may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which XYLOCAINE 10 mg/0,1 ml affects you (see section 4).

Depending on the dosage, XYLOCAINE 10 mg/0,1 ml may have a very mild effect on mental function and may temporarily affect your locomotion and coordination, e.g. affect your ability to drive vehicles or to use machinery.

XYLOCAINE 10 mg/0,1 ml contains alcohol

XYLOCAINE 10 mg/0,1 ml contains 23,136 % *m/v* of alcohol (ethanol) in each 0,1 ml. The amount in 0,1 ml of XYLOCAINE 10 mg/0,1 ml is equivalent to less than 1 ml beer or 1 ml wine.

The small amount of alcohol in XYLOCAINE 10 mg/0,1 ml will not have any noticeable effects.

3. How XYLOCAINE 10 mg/0,1 ml will be administered to you

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

You will not be expected to give yourself XYLOCAINE 10 mg/0,1 ml. It will be given to you by a person who is qualified to do so.

Your doctor will tell you how long your treatment with XYLOCAINE 10 mg/0,1 ml will last.

If you have the impression that the effect of XYLOCAINE 10 mg/0,1 ml is too strong or too weak, tell your doctor/dentist or pharmacist.

A short plastic spray nozzle is included in each pack. Do not cut or shorten the nozzle. The short spray nozzle is already bent to its final appearance and no further action is required before using the spray nozzle.

Nozzles should not be reused and should be discarded immediately after use.

If you have been given more XYLOCAINE 10 mg/0,1 ml than you should

Since a healthcare provider will administer XYLOCAINE 10 mg/0,1 ml, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

The first signs that too much XYLOCAINE 10 mg/0,1 ml has been used usually take the form of light-headedness, dizziness and sometimes blurred vision. In the event of a serious overdosage, trembling, seizures or unconsciousness may occur.

If the early signs of overdosage are noticed and no further XYLOCAINE 10 mg/0,1 ml is given, the risk of serious adverse effects occurring rapidly decreases. If you notice any of these signs, contact a doctor immediately.

If you forget to use XYLOCAINE 10 mg/0,1 ml

Since a healthcare provider will administer XYLOCAINE 10 mg/0,1 ml, it is unlikely that the dose will be missed.

4. Possible side effects

XYLOCAINE 10 mg/0,1 ml can have side effects.

Not all side effects reported for XYLOCAINE 10 mg/0,1 ml are included in this leaflet. Should your general health worsen or if you experience any untoward effects while XYLOCAINE 10 mg/0,1 ml is being administered to you, please consult your healthcare provider for advice.

If any of the following happens, stop using XYLOCAINE 10 mg/0,1 ml 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,
- anaphylactic reaction, fever, fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to XYLOCAINE 10 mg/0,1 ml. 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:

- seizures/convulsions (fits), state of unconsciousness in which a person cannot be awakened (coma),
- condition in which not enough oxygen passes from your lungs into your blood causing shortness of breath, bluish tint in the face and lips and confusion (respiratory failure),
- decreased heart muscle function (myocardial depression), slow heartbeat (bradycardia), irregularity of the heartbeat (dysrhythmia), sudden unexpected loss of heart function, breathing and consciousness (cardiac arrest).

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

Side effects with an unknown frequency:

- increased amount of XYLOCAINE 10 mg/0,1 ml absorbed in the blood if too much is given or by accidental intravenous injection or by absorption of large amounts through mucous membranes (skin lining the mouth, nose or eyelids etc), damaged skin or from areas with a large amount of blood vessels,
- restlessness, excitement, nervousness, dizziness, drowsiness,
- feelings of sadness, worthlessness, thoughts of suicide or death (depression),
- ringing in the ears (tinnitus),
- blurred vision,

- nausea, vomiting,
- muscle twitching, unintentional muscle movement involving to-and-fro movements of one or more parts of the body (tremors),
- local irritation at the application site,
- reversible symptoms such as sore throat, hoarseness and loss of voice may occur following application to the lining of the larynx (laryngeal mucosa) before a tube is placed through the mouth or nose (endotracheal intubation),
- dilatation of blood vessels (peripheral vasodilation), low blood pressure (hypotension).

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: <https://www.sahpra.org.za/health-productsvigilance/>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of XYLOCAINE 10 mg/0,1 ml.

5. How to store XYLOCAINE 10 mg/0,1 ml

Store all medicines out of reach of children.

Store at or below 25 °C in well closed containers.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Your doctor/dentist or the hospital will normally store XYLOCAINE 10 mg/0,1 ml. The staff are responsible for storing, using and disposing of the pump spray in the correct way.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What XYLOCAINE 10 mg/0,1 ml contains

The active substance is 10 mg of lidocaine.

The other ingredients are essence of banana, ethanol, levomenthol, polyethylene glycol 400, saccharin and purified water.

Contains alcohol: Ethanol 23,136 % *m/v*

Contains sweetener: Saccharin 0,15 mg

Sugar free

What XYLOCAINE 10 mg/0,1 ml looks like and contents of the pack

A clear or almost clear, slightly coloured liquid (pale pink or pale yellow) with an odour of banana, ethanol and levomenthol packed in a glass bottle with a dose valve.

50 ml is packed into a colourless, neutral, moulded glass vial with a plastic and metal pump mechanism (dose valve) with a plastic dip tube suitable for a 50 ml bottle, together with a short, bent polypropylene spray nozzle (applicator) consisting of a cap, tube and tip with hole for spraying.



Each bottle provides 475 spray doses in a 50 ml pack size, with a short plastic spray nozzle approximately 120 mm long. Additional short spray nozzles are available separately.

Long plastic spray nozzles are available separately.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

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G 2826 (Act 101/1965)

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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