

XYLOCAINE(R) INJECTION

Lignocaine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Xylocaine. It does not contain all the information that is known about Xylocaine.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Xylocaine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What XYLOCAINE is for

Xylocaine is used to prevent or relieve pain, but it will not put you to sleep.

Xylocaine is also used after surgery to relieve pain. It can also be used to make childbirth less painful.

Xylocaine belongs to a group of medicines called local anaesthetics. It is injected into the body where it makes the nerves unable to pass messages to the brain.

Depending on the amount used, Xylocaine will either totally stop pain or will cause a partial loss of

feeling.

Xylocaine is sometimes combined with adrenaline to make it last longer. Adrenaline makes the blood vessels at the site of injection narrower, which keeps the Xylocaine where it is needed for a longer time.

Your doctor will have explained why you are being treated with Xylocaine and told you what dose you will be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

Xylocaine is not addictive.

Before you are given XYLOCAINE

When you must not use it

If you are pregnant or breastfeeding do not use Xylocaine unless your doctor says so. Ask your doctor about the risks and benefits of using this medicine while you are pregnant or breastfeeding.

Xylocaine has been widely used during pregnancy and there have been no reports of any ill effects on the baby. It can be used during childbirth.

Your baby can take in very small amounts of Xylocaine from breast milk if you are breastfeeding, but it is unlikely that the amount available to the baby will do any harm.

Xylocaine will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

Before you are given it

You must tell your doctor if:

1. you have any allergies to

- * any ingredients listed at the end of this leaflet
- * other local anaesthetics eg. bupivacaine
- * other substances

If you have an allergic reaction, you may get a skin rash, hay fever or an asthma attack.

2. you have any of these medical conditions

- * problems with your blood pressure or circulation
- * blood poisoning
- * problems with the clotting of your blood
- * nerve problems, e.g. epilepsy
- * heart, liver or kidney problems
- * thyroid problems
- * malignant hyperthermia
- * diabetes
- * skin infections

It may not be safe for you to take Xylocaine if you have any of these conditions.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

- * ones to control your heart beat
- * ones for blood pressure (anti-hypertensives)
- * ones for epilepsy or fits
- * ones for depression
- * cimetidine
- * any medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way Xylocaine works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell them before you are given any Xylocaine.

How XYLOCAINE is given

Xylocaine will be injected by your doctor into the skin, near a single nerve, or into an area which contains a large number of nerves.

This will result in an area of numbness at the site of injection, near the site of injection or in an area that may seem unrelated to the site of injection. The last will be the case if you are given an EPIDURAL injection (an injection around the spinal cord).

Xylocaine should not be injected directly into the blood.

The dosage you will be given will depend on your body size, age and the type of pain relief required. Your doctor will have had a lot of experience injecting Xylocaine or other local anaesthetics and will choose the best dose for you. They will be willing to discuss this decision with you.

Overdose

The doctor giving you Xylocaine will be experienced in the use of local anaesthetics, so it is unlikely that you will be given an overdose.

However, if you are particularly sensitive to Xylocaine, or the dose is accidentally injected directly into your blood, you may develop problems for a short time with your sight or hearing. You may get a numb feeling in or around the mouth, feel dizzy or stiff, or have twitchy muscles.

Whenever you are given Xylocaine, equipment will be available to care for you if an overdose happens.

While you are being given it

Things to be careful of

Be careful driving or operating machinery after you have been given Xylocaine.

You may be drowsy and your reflexes may be slow.

Do not drink alcohol while you are being given Xylocaine.

If you drink alcohol while you are being given Xylocaine your blood pressure may drop making you feel dizzy and faint.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Xylocaine.

Xylocaine will help relieve pain in most people, but it may have unwanted side-effects. All medicines can have side effects. Sometimes

they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor or nurse if you notice any of the following and they worry you:

- * tremors
- * nervousness
- * dizziness
- * blurred vision
- * drowsiness
- * ringing in the ears
- * numbness
- * feeling strange (disoriented)
- * nausea (feeling sick)
- * vomiting

These are all mild side effects of Xylocaine.

After an epidural injection you may develop a headache or backache which is not related to the medicine used. These can, on rare occasions, last for some months after the injection is given.

If Xylocaine is given wrongly, or you are very sensitive to it, it sometimes causes

- * fits
- * unconsciousness
- * breathing problems
- * low blood pressure
- * slow heart beat
- * collapse

If you are sensitive to sodium metabisulphite (found in adrenaline containing preparations), it may cause life-threatening reactions or less severe asthmatic episodes.

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

Some people may get other side effects while being given Xylocaine.

Tell your doctor if you notice anything else that is making you feel unwell.

After using it

Storage

Xylocaine will be stored by your doctor or pharmacist under the recommended conditions.

2mL and 5mL Polyamp presentations, Xylocaine with adrenaline in glass ampoules and single dose vials should be kept in a cool dry place where the temperature stays below 25 degrees C.

20mL Polyamp presentations, Xylocaine in glass ampoules should be kept in a cool dry place where the temperature stays below 30 degrees C.

Disposal

Any Xylocaine from a single dose preparations which is not used, will be disposed of in a safe manner by your doctor or pharmacist.

Product description

Xylocaine plain and adrenaline containing solutions are clear and colourless.

Each Xylocaine plain solution contains Lignocaine hydrochloride as the active ingredient

plus

Sodium chloride

Sodium hydroxide

Water for Injections.

Each Xylocaine WITH ADRENALINE solution contains Lignocaine hydrochloride and Adrenaline Acid Tartrate as the active ingredients

plus

Sodium chloride

Sodium hydroxide

Sodium metabisulfite (E223)

Water for Injections.

The exceptions are Xylocaine 1% with Adrenaline 1:100,000 and Xylocaine 2% with Adrenaline 1:80,000 5mL ampoules which may also use Hydrochloric acid for pH adjustment.

In the USA, lignocaine is known as lidocaine and adrenaline as epinephrine.

For a full list of Xylocaine products see next page.

Manufacturer

AstraZeneca Pty Ltd

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NORTH RYDE NSW 2113

Tel: 1-800-805-342

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What is in Xylocaine(R)

XYLOCAINE 0.5%

contains lignocaine hydrochloride 5.3mg/mL (equivalent to lignocaine hydrochloride anhydrous 5mg/mL)

in

50 x 5mL polyethylene ampoules Polyamp(R)

AUST R 12009

XYLOCAINE 0.5% with adrenaline 1:200,000

contains lignocaine hydrochloride 5.3mg/mL (equivalent to lignocaine hydrochloride anhydrous 5mg/mL) and adrenaline acid tartrate 0.0091mg/mL

in

20mL* single dose vials

AUST R 12008

XYLOCAINE 1%

contains lignocaine hydrochloride 10.7mg/mL (equivalent to lignocaine hydrochloride anhydrous 10mg/mL)

in

50 x 5mL glass ampoules

AUST R 48357

50 X 2mL polyethylene ampoules Polyamp(R)

AUST R 12013

10 x 5mL polyethylene ampoules Polyamp(R)

AUST R 48357

50 x 5mL polyethylene ampoules Polyamp(R)

AUST R 48357

5 x 20mL polyethylene ampoules Polyamp(R)

AUST R 48361

XYLOCAINE 1% with adrenaline 1:100,000

contains lignocaine hydrochloride 10.7mg/mL (equivalent to lignocaine hydrochloride anhydrous 10mg/mL) and adrenaline acid tartrate 0.0182mg/mL

in

50 x 5mL* glass ampoules

AUST R 12017

XYLOCAINE 1% with adrenaline 1:200,000

contains lignocaine hydrochloride 10.7mg/mL (equivalent to lignocaine hydrochloride anhydrous 10mg/mL) and adrenaline acid tartrate 0.0091mg/mL

in

5 x 20mL* single dose vials

AUST R 12015

**XYLOCAINE 1.5% with
adrenaline 1:200,000**

contains lignocaine hydrochloride
16mg.mL (equivalent to lignocaine
hydrochloride anhydrous 15mg/mL)
and adrenaline acid tartrate
0.0091mg/mL

in

5 x 20mL* single dose vials

AUST R 12011

XYLOCAINE 2%

contains lignocaine hydrochloride
21.3mg.mL (equivalent to lignocaine
hydrochloride anhydrous 20mg/mL)

in

50 x 5mL glass ampoules

AUST R 48362

50 x 2mL polyethylene ampoules

Polyamp(R)

AUST R 12020

10 x 5mL polyethylene ampoules

Polyamp(R)

AUST R 48362

50 x 5mL polyethylene ampoules

Polyamp(R)

AUST R 48362

5 x 20mL polyethylene ampoules

Polyamp(R)

AUST R 48364

**XYLOCAINE 2% with adrenaline
1:80,000**

contains lignocaine hydrochloride
21.3mg.mL (equivalent to lignocaine
hydrochloride anhydrous 20mg/mL)
and adrenaline acid tartrate
0.0227mg/mL

in

10 x 5mL* glass ampoules

AUST R 54520

**XYLOCAINE 2% with adrenaline
1:200,000**

contains lignocaine hydrochloride
21.3mg.mL (equivalent to lignocaine
hydrochloride anhydrous 20mg/mL)
and adrenaline acid tartrate
0.0091mg/mL

in

5 x 20mL* single dose vials

AUST R 12021

* contains sodium metabisulfite