

Package leaflet: Information for the user

Xylocaine® 2% with Adrenaline (Epinephrine) (1:200,000) Solution for Injection anhydrous lidocaine hydrochloride / adrenaline (epinephrine)

Read all of this leaflet carefully before this medicine is given to you because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. See section 4.

What is in this leaflet:

1. What Xylocaine with adrenaline is and what it is used for
2. What you need to know before Xylocaine with adrenaline is given to you
3. How Xylocaine with adrenaline is given to you
4. Possible side effects
5. How to store Xylocaine with adrenaline
6. Contents of the pack and other information

1. What Xylocaine with adrenaline is and what it is used for

The name of your medicine is 'Xylocaine 2% with Adrenaline (Epinephrine) (1:200,000)'. It is referred to as 'Xylocaine with adrenaline' in the rest of this leaflet.

Xylocaine with adrenaline is used to numb (anaesthetise) part of the body for surgical operations or to provide pain relief.

Xylocaine with adrenaline is used in adults and children above 12 years to:

- numb (anaesthetise) the area of the body where surgery is to be performed.
- provide pain relief in labour, after surgery or after acute injury.
- treat certain types of chronic pain.

Xylocaine with adrenaline contains two different medicines: lidocaine and adrenaline (epinephrine). Each of these works in a different way.

- Lidocaine belongs to a group of medicines called local anaesthetics. These medicines numb (anaesthetise) parts of the body.
- Adrenaline belongs to a group of medicines called vasoconstrictors. These medicines make the blood vessels where the injection is given narrower. This means you will bleed less and the effects of the medicine will last longer.

2. What you need to know before Xylocaine with adrenaline is given to you

You must not be given Xylocaine with adrenaline:

- if you are allergic to lidocaine, adrenaline or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to any other local anaesthetics.

You must not be given Xylocaine with adrenaline if any of the above apply to you. If you are not sure, talk to your doctor or nurse before you are given it.

Warnings and precautions

Talk to your doctor or nurse before having Xylocaine with adrenaline:

- if you have high blood pressure or heart problems such as a slow heart beat.
- if you have liver or kidney problems.

- if you have difficulty breathing.
- if you have epilepsy.
- if you have diabetes.
- if you have thyroid problems.
- if you have a decreased blood supply to your brain.
- if you have an infection or inflammation at the site where the injection is to be given.
- if you have ever been told that you have a rare disease of the blood pigment called 'porphyria' or anyone in your family has it.

If you are not sure if any of the above apply to you, talk to your doctor nurse before having Xylocaine with adrenaline.

Other medicines and Xylocaine with adrenaline

Tell your doctor if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Xylocaine with adrenaline can affect the way some medicines work and some medicines can have an effect on Xylocaine with adrenaline.

In particular, tell your doctor if you are taking any of the following medicines:

- Other local anaesthetics.
- Other medicines that contain adrenaline.
- Halothane (a general anaesthetic).
- Medicines used to treat an uneven heart beat (arrhythmia) such as amiodarone.
- Beta-blockers medicines such as propranolol.
- Butyrophenone medicines for sickness, such as domperidone.
- Other butyrophenone medicines for mental problems, such as haloperidol.
- Phenothiazine medicines for mental problems, such as chlorpromazine.
- Medicines for depression such as monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants.
- Medicines that induce labour.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given Xylocaine with adrenaline.

Driving and using machines

Xylocaine with adrenaline may make you feel sleepy and affect the speed of your reactions. After you have been given Xylocaine with adrenaline, you should not drive or use tools or machines until the next day.

Xylocaine with adrenaline contains sodium, methyl parahydroxybenzoate and sodium metabisulphite

- This medicine contains 2.49 mg sodium (main component of cooking/table salt) in each millilitre (ml). This is equivalent to 0.125 % of the recommended maximum daily dietary intake of sodium for an adult.
- Xylocaine with adrenaline contains methyl parahydroxybenzoate (E218). This may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.
- Xylocaine with adrenaline contains sodium metabisulphite (E223). This may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How Xylocaine with adrenaline is given to you

Xylocaine with adrenaline will be given to you by a doctor. It will be given to you as an injection. Your doctor will know the correct way to give you this medicine.

The dose that your doctor gives you will depend on the type of pain relief that you need. It will also depend on your body size, age, physical condition and the part of your body that the medicine is being injected into. You will be given the smallest dose possible to produce the required effect.

Xylocaine with adrenaline will usually be given near the part of the body to be operated on. It stops the nerves from being able to pass pain messages to the brain. It will stop you feeling pain. It will start to work a few minutes after being injected and will slowly wear off when the medical procedure is over.

If you have been given too much Xylocaine with adrenaline

Serious side effects from getting too much Xylocaine with adrenaline need special treatment and the doctor treating you is trained to deal with these situations. The first signs of being given too much Xylocaine with adrenaline are usually as follows:

- Feeling dizzy or light-headed.
- Numbness of the lips and around the mouth.
- Numbness of the tongue.
- Hearing problems.
- Problems with your sight (vision).

To reduce the risk of serious side effects, your doctor will stop giving you Xylocaine with adrenaline as soon as these signs appear. This means that if any of these happen to you, or you think you have received too much Xylocaine with adrenaline, **tell your doctor immediately**.

More serious side effects from being given too much Xylocaine with adrenaline include problems with your speech, irrational behaviour, twitching of your muscles, fits (seizures), effects on your heart and blood vessels, loss of consciousness, coma and stopping breathing for a short while (apnoea).

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

Severe allergic reactions (rare, may affect up to 1 in 1,000 people)

If you have a severe allergic reaction, **tell your doctor immediately**. The signs may include sudden onset of:

- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet and ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

Other possible side effects:

- Numbness where the injection is given. This will go away slowly.

Common (may affect up to 1 in 10 people)

- Low blood pressure. This might make you feel dizzy or light-headed.
- High blood pressure.
- Feeling sick (nausea) or being sick (vomiting).
- Pins and needles.
- Feeling dizzy.
- Slow heart beat.

Uncommon (may affect up to 1 in 100 people)

- Ringing in the ears (tinnitus) or being sensitive to sound.
- Difficulty in speaking.
- Numbness of the tongue or around the mouth.
- Fits (seizures).
- Feeling sleepy.
- Shakiness.
- Blurred vision.

Rare (may affect up to 1 in 1,000 people)

- Uneven heart beat (arrhythmias).

- Nerve damage that may cause changes in sensation or muscle weakness (neuropathy). This may include peripheral nerve damage.
- A condition called arachnoiditis (inflammation of a membrane that surrounds the spinal cord). The signs include a stinging or burning pain in the lower back or legs and tingling, numbness or weakness in the legs.
- Double vision.
- Slowed or stopped breathing or stopped heart beat.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xylocaine with adrenaline

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the vial and outer carton after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C - 8°C).
- Keep the vial in the outer carton in order to protect from light.
- Your doctor or the hospital will normally store Xylocaine with adrenaline and they are responsible for the quality of the product when it has been opened if it is not used immediately. They are also responsible for disposing of any unused Xylocaine with adrenaline correctly.

6. Contents of the pack and other information

What Xylocaine with adrenaline contains

The active substances are anhydrous lidocaine hydrochloride and adrenaline (epinephrine). Each millilitre (ml) of solution contains 20 milligrams of anhydrous lidocaine hydrochloride as lidocaine hydrochloride (400 mg per 20 ml vial) and 5 micrograms of adrenaline (epinephrine) as the acid tartrate (100 micrograms per 20 ml vial).

The other ingredients are sodium chloride, sodium metabisulphite (E223), methyl parahydroxybenzoate (E218), sodium hydroxide, hydrochloric acid and water for injections.

What Xylocaine with adrenaline looks like and contents of the pack

Xylocaine with adrenaline is a clear, colourless, solution for injection. It comes in multi-dose vials of 20 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

Tel: +353 (0)1 6308400

Manufacturer:

AstraZeneca UK Ltd, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK

Or

Recipharm Monts, Usine de Monts, 18 Rue de Montbazou, F-37260, Monts, France

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