

PACKAGE LEAFLET

Package leaflet: Information for the user

Xylocaine® 2% w/v with Adrenaline (epinephrine) 1:80,000 DENTAL Solution for injection

Lidocaine Hydrochloride Anhydrous 2% w/v Adrenaline (epinephrine) 1:80,000

Read all of this leaflet carefully before you start taking this medicine 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 dentist or doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- Normally a dentist or dental hygienist will use this product on you in the dental surgery. It is unlikely that you will be permitted to take this medicine home.
- If you get any side effects, talk to your dentist or doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL is and what it is used for

Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL is a solution for injection. It contains lidocaine and adrenaline.

Lidocaine is a type of medicine called a local anaesthetic (anaesthetics are medicines which numb an area of the body). Adrenaline is a type of medicine called a vasoconstrictor (these are medicines which make the blood vessels at the site of injection narrower) which means that you will bleed less and the effects of the medicine will last longer.

It is used to stop pain during dental procedures.

2. What you need to know before being given Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL

Do not use Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL:

- if you are allergic to lidocaine or any of the other ingredients of this medicine (listed in section 6). if you are allergic to certain chemicals called as sulphites, especially so if you suffer from asthma which is treated by your doctor with medications called as “steroids”, as it may cause severe allergic reaction (anaphylactic shock) or breathlessness (bronchospasm).

- if you have ever had an allergic reaction to another local anaesthetic.

Warnings and precautions

Talk to your dentist or doctor before being given Xylocaine 2% w/v with Adrenaline (epinephrine) 1:80,000 DENTAL.

Tell your dentist or doctor if any of the following apply to you:

- if you have high blood pressure or any heart problems, in particular a slow heartbeat
- if you have anaemia or other blood disorder
- if you have epilepsy
- if you have ever had a stroke
- if you have problems with your liver or kidneys
- if you have problems with your thyroid
- if you have breathing problems
- if you have a condition which reduces your respiratory function
- if you have uncontrolled diabetes mellitus
- if you are in poor general condition
- if you are pregnant or think you might be pregnant
- if you are breast feeding
- if you have an infection at the site where the injection is to be given
- if you have acidosis or generally low oxygen in blood (hypoxia)

Other medicines and Xylocaine 2% w/v with Adrenaline (epinephrine) 1:80,000 DENTAL

Tell your dentist or doctor if you are taking, have recently been treated with, or have recently taken any other medicines.

Make sure your dentist or doctor knows if you are taking any of the medicines listed here:

- antidepressants (MAOI's) monoamine oxidase inhibitors (for example, phenelzine and isocarboxazid)
- tricyclic antidepressants (for example, imipramine, amitriptyline, doxepin, mianserin, trazodone and lofepramine)
- medicines used for treating mental problems such as psychosis (for example phenothiazines, butyrophenones)
- beta blockers medicines such as propranolol
- medicines used to treat an irregular heartbeat (arrhythmias) such as amiodarone or mexiletine
- anaesthetic gases (e.g., halothane and enflurane) used for general anaesthesia
- any other local anaesthetics

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your dentist or doctor for advice before being given this medicine.

Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL contains sodium metabisulfite and sodium

- Sodium metabisulfite (E223) may rarely cause severe hypersensitivity reactions and bronchospasm. This may be manifested as a rash, swelling, low blood pressure and breathlessness and may be more prevalent in people with a history of allergies and asthma.

- This product contains less than 1 mmol sodium (23 mg) per ml. i.e. essentially “sodium free”

3. How Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL will be given

You will be given Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL as an injection by your dentist, who will decide what dose is right for you.

The usual dose is between 1 to 5 ml (= 20-100 mg lidocaine hydrochloride) for effective local anaesthesia in most dental procedures. In all cases, the smallest dose that results in effective anaesthesia should be used.

Use in older people

Dose adjustment should be considered for unwell and older people and should be given smaller doses.

Use in children and adolescents

The quantity injected will be determined by doctor based on the age and weight of the child and the amount or type of required dental treatment.

Children will be given smaller doses in relation to their body weight. An adequate dose ranges from 20 mg to 40 mg of lidocaine hydrochloride (1-2 ml) per treatment session in children under 10 years of age. Adolescents (12 to 18 years of age) will be given the same doses as adults (1 to 5 ml; 20-100 mg lidocaine hydrochloride).

You may receive an injection of this medicine inside your mouth before receiving dental treatment. Your dentist will wait a few minutes for the area to go numb before starting the treatment, so that you will feel less pain. The numbness will last until the treatment is finished and for a while afterwards.

After the injection, your mouth may feel numb for some time. Take care not to accidentally bite your tongue or cheek. Also, avoid drinking very hot drinks and eating very hot food until the feeling fully returns. The numbness will slowly go away.

If you feel you have been given too much or too little Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL, talk to your dentist or doctor **immediately**.

If you have any further questions on the use of this medicine, ask your dentist or doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These side effects are rare and usually only occur with high doses.

If you have any of the following rare side effects while taking your medicine tell your dentist immediately, or go straight to the hospital if you have left the dental surgery.

- Severe allergic reaction may include a red and lumpy skin rash, difficulty in breathing, lowered blood pressure, swelling of the face, mouth, lips or eyelids.

Other side effects may include:

- Feeling of nervousness, feeling sleepy, unsteadiness, ringing in the ears (tinnitus), headache, and unconsciousness.
- Low blood pressure, which might make you feel dizzy or light-headed

- Fits (seizures)
- Restlessness, anxiety, disorientation
- Eye pain, watering of eyes, blurred vision or other problems with your sight
- Altered taste sensation
- Faster heart beats or pulse, slower heart beats or pulse, uneven heart beat, slowed or stopped breathing or stopped heart beat
- Difficulty in breathing
- Nausea (feeling sick) and vomiting
- Skin rash and redness
- Sensation of tingling, tickling, pricking, or burning of skin
- Pain in joints or muscles
- Pain and wound at the injection site
- Numbness of tongue or around the mouth and where the injection is given.
- Swelling of the face, mouth, lips or eyelids, chills

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist 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 (in Ireland) or via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard (in the United Kingdom). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL

You will not normally be asked to store your medicine as it will be given to you by a healthcare professional.

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 container after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. Keep the container in the outer carton in order to protect from light.

Do not use this medicine if you notice any appearance of cloudiness or colour.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL contains

- The active substances are: Each ml of solution contains Lidocaine Hydrochloride equivalent to lidocaine hydrochloride anhydrous 20 mg (44 mg per 2.2 ml cartridge), and Adrenaline (Epinephrine) tartrate equivalent to adrenaline (epinephrine) 12.5 micrograms (27.5 micrograms per 2.2 ml cartridge).
- The other ingredients are: sodium chloride, sodium metabisulfite (E223), sodium hydroxide, hydrochloric acid and water for injections.

What Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL looks like and contents of the pack

A clear, colourless, aqueous sterile solution. Solution for injection for dental use.

Each glass cartridge contains 2.2 ml of Xylocaine 2% with Adrenaline (epinephrine) 1:80,000 DENTAL.

Each pack contains 50 or 100 cartridges.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

DENTSPLY DeTrey GmbH

De-Trey-Strasse 1

78467 Konstanz,

Germany

Manufacturer:

Pierrel S.p.A., Strada Statale, Appia 46/48 81043, Capua (CE), Italy

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The following information is intended for healthcare professionals only:

Adequate precautions are required to avoid prolonged contact between local anaesthetic solutions containing adrenaline (low pH) and metal surfaces (e.g. needles or metal parts of syringes), since dissolved metal ions, particularly copper ions, may cause severe local irritation (swelling, oedema) at the site of injection and accelerate the degradation of adrenaline.

The solution must be used immediately after opening the cartridge.

The dental cartridge should be disinfected by wiping with a pledget moistened with disinfectant. The cartridge should not be immersed in disinfectant solution.

Xylocaine with adrenaline cartridges should not be autoclaved.