What you should know about your medicine.

Please read all of this leaflet before you are given this medicine

- 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. Do not pass it onto others. It may harm them, even if their symptoms 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 any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your dentist or doctor.

In this leaflet:
1. What Xylocaine® 2% with Adrenaline (epinephrine) 1:80,000 DENTAL is and what it is used for
2. Before being given Xylocaine® 2% with Adrenaline (epinephrine) 1:80,000 DENTAL
3. How Xylocaine® 2% with Adrenaline (epinephrine) 1:80,000 DENTAL will be given
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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.

What this medicine is used for
It is used to stop pain during dental procedures.

2. 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 (hypersensitive) to Xylocaine or any of the ingredients of Xylocaine 2% with
Adrenaline (epinephrine) 1:80,000 DENTAL (see section 6 – Further Information)
- if you have ever had an allergic reaction to another local anaesthetic
to numb the fingers, toes, nose, ear lobes or penis as an injection directly into the vein.

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
- if you have problems with your thyroid
- if you have breathing problems
- 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
Using other medicines
Make sure your dentist or doctor knows if you are taking any of the medicines listed here:

- anti depressants (MAOI’s) monoamine oxidase inhibitors (for example, phenelzine and isocarboxazid)
- tricyclic anti depressants (for example, imipramine, amitriptyline, doxepin, mianserin, trazodone and lofepramine)
- any other anaesthetics

Tell your dentist or doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
If you are pregnant, think you might be pregnant or are breast-feeding, ask your dentist or doctor for advice before being given Xylocaine® 2% with Adrenaline (epinephrine) 1:80,000 DENTAL.

Important Information about some of the ingredients of Xylocaine® 2% with Adrenaline (epinephrine) 1:80,000 DENTAL

- 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 (23mg) 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.

You may have this injection inside your mouth before having your 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.

- Your dentist will decide what dose is right for you
- The maximum dose is 500mg (25ml)

Adults
- The usual dose is between 1 to 2ml.

Children, the elderly and unwell patients
- A smaller dose should be given depending on age and how unwell they are
- In all cases, the smallest dose that is needed should be used

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.

Xylocaine Injection will be given to you by the dentist or doctor.

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

4. Possible side effects
Like all medicines, Xylocaine® 2% with Adrenaline (epinephrine) 1:80,000 DENTAL can cause side effects, as well as the effects that are needed. 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.
Rare side effects (affecting fewer that 1 in 1,000 people)

- Feelings of nervousness, dizziness, blurred vision, shakiness, sounds/ringing in the ears, and occasionally drowsiness and loss of consciousness.
- Fits
- Low blood pressure
- Nausea, headache, or a faster heartbeat.
- A slow (rarely stopped) heart beat or breathing

If any of these side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or dentist.

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 out of the sight and reach of children.
- 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 Xylocaine® 2% with Adrenaline (epinephrine) 1:80,000 DENTAL after the expiry date which is printed on the container after EXP. The expiry date refers to the last day of the month.
- Do not use if there is any appearance of cloudiness or colour.

6. Further information

What Xylocaine® 2% with Adrenaline (epinephrine) contains

- Each ml of solution contains Lidocaine Hydrochloride equivalent to lidocaine hydrochloride anhydrous 20 mg (36 mg per 1.8 ml cartridge or 44 mg per 2.2 ml cartridge), and Adrenaline (Epinephrine) tartrate equivalent to adrenaline (epinephrine) 12.5 micrograms (22.5 micrograms per 1.8 ml cartridge or 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 1.8ml or 2.2ml of Xylocaine® 2% with Adrenaline (epinephrine) 1:80,000 DENTAL.

Each pack contains 100 cartridges.

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