PACKAGE LEAFLET: INFORMATION FOR THE USER

Xylocaine[®] 10 mg Spray lidocaine

Read all of this leaflet carefully before Xylocaine spray is given to you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, dentist or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or dentist.

In this leaflet:

- 1. What Xylocaine Spray is and what it is used for
- 2. Before Xylocaine Spray is given to you
- 3. How Xylocaine Spray is given to you
- 4. Possible side effects
- 5. How to store Xylocaine Spray
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1. What Xylocaine Spray is and what it is used for

The name of your medicine is 'Xylocaine 10 mg Spray'. It is referred to as 'Xylocaine Spray' in the rest of this leaflet.

Xylocaine Spray contains a medicine called lidocaine. This belongs to a group of medicines called local anaesthetics.

Xylocaine Spray is used to numb (anaesthetise) parts of the body. It stops pain happening during:

- Medical examinations and operations of the nose and throat.
- Childbirth, and after the birth if stitches are needed.
- Treatment at the dentist.

2. Before Xylocaine Spray is given to you

You must not be given Xylocaine Spray if:

- You are allergic (hypersensitive) to lidocaine or any of the other ingredients of Xylocaine Spray (see Section 6: Further information).
- You are allergic to any other local anaesthetics of the same class (such as prilocaine or bupivacaine).

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

Take special care with Xylocaine Spray

Check with your doctor or dentist before having Xylocaine Spray if:

- You have any cuts, sores or ulcers in your throat, mouth or nose.
- You have a chest infection.
- You have epilepsy.
- You have heart problems such as a slow heart beat.
- You have very low blood pressure.
- You have liver or kidney problems.
- 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 before having Xylocaine Spray.

Taking other medicines

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

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

• Medicines used to treat an uneven heart beat (arrhythmia) such as mexiletine.

Pregnancy and breast-feeding

Before you are given Xylocaine Spray, tell your doctor or dentist if you are pregnant, planning to get pregnant, or if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

- Xylocaine Spray may affect you being able to drive or use tools or machines. This depends on where in the body Xylocaine Spray is used and how much is used.
- Your doctor or dentist will tell you when it is safe for you to do these activities.

Important information about some of the ingredients of Xylocaine Spray

- Xylocaine Spray contains saccharin. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before using this medicine.
- The banana flavouring in Xylocaine Spray contains propylene glycol. Propylene glycol may cause skin irritation.

3. How Xylocaine Spray is given to you

- Xylocaine Spray will usually be given to you by a doctor or dentist. The dose that your doctor or dentist gives you will depend on the type of pain relief that you need. It will also depend on your age and physical condition.
- If you are given Xylocaine Spray to take home, you must use the dose recommended by your doctor or dentist. Always use Xylocaine Spray exactly as your doctor or dentist has told you. You should check with them if you are not sure.

How to use Xylocaine Spray

- Do not use more than 20 sprays.
- You should use as few sprays as possible.
- Do not get the spray in your eyes.
- The spray nozzle is bent so that it works properly. Do not try to change the shape of the nozzle or it might break.

How to use Xylocaine Spray in the mouth and throat

- When Xylocaine Spray is used in the mouth and throat it causes a loss of feeling. This makes it more likely that food or liquid may go down the wrong way. Also, this may make it difficult to swallow or cause some people to accidentally bite their tongue or cheek.
- Xylocaine Spray should be used with care in the elderly, in people who are in poor general health and in children.

If you use more Xylocaine Spray than you should

If you think you have used more Xylocaine Spray than you should, talk to your doctor or dentist immediately.

4. **Possible side effects**

Like all medicines, Xylocaine Spray may cause side effects although not everybody gets them.

Severe allergic reactions:

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:

- Irritation where Xylocaine Spray has been used.
- Feeling nervous.
- Feeling dizzy.
- Feeling sleepy.
- Loss of consciousness.
- Sore throat.
- Hoarse voice or loss of voice.
- Low blood pressure. This might make you feel dizzy or light-headed.
- Fits (seizures).
- Difficulty breathing or slow breathing.
- Slow heart beat.
- Stopped breathing or a stopped heart beat.

Do not be concerned by this list of possible side effects. You may not get any of them. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or dentist.

5. How to store Xylocaine Spray

- Keep out of the reach and sight of children.
- Do not use after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. At temperatures below 8°C the spray solution may start to go solid. This will dissolve when the spray solution is warmed up gently to room temperature.
- The nozzles should not be re-used and should be disposed of immediately after use.
- Your doctor/dentist or the hospital will normally store Xylocaine Spray. The staff are responsible for the storing, using and disposing of the spray in the correct way.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. Further information

What Xylocaine Spray contains

The active ingredient is lidocaine. Each dose of spray contains 10 mg of lidocaine.

The other ingredients are ethanol, levomenthol, macrogol 400, essence of banana (contains propylene glycol), saccharin and purified water.

What Xylocaine Spray looks like and contents of the pack

Xylocaine Spray is a pump spray. It comes in a 50 ml bottle. Each bottle contains about 500 sprays.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Xylocaine Spray is held by AstraZeneca UK Ltd, 600 Capability Green, Luton, LU1 3LU, UK.

Xylocaine Spray is manufactured by AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name	Reference Number
Xylocaine Spray	17901/0177

This is a service provided by the Royal National Institute of Blind People.

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