Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Xylocaine 10% Pump Spray. It does not contain all the information that is known about Xylocaine 10% Pump Spray.

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

All medicines have risks and benefits.

If you have any concerns about using this medicine, ask your doctor, pharmacist or

Keep this leaflet.

You may need to read it again.

What Xylocaine 10% Pump Spray is used for

Xylocaine 10% Pump Spray may be used for the following reasons:

- To produce temporary loss of sensation in a part of the body before certain types of examination and instrumentation are performed by your doctor eg examination of your lungs. This may also help prevent coughing or gagging from the procedures.
- To help prevent pain associated with minor surgical procedures in the ear, nose and throat
- To help prevent pain during the puncture of a cavity of the upper jaw (the maxillary sinus)
- To help prevent pain and or discomfort at the dentist eg prior to injection
- During general anaesthesia to prevent
- To help prevent pain during the final stages of childbirth, before the cutting or stitching of the perineum (skin between the vagina and anus)

Xylocaine 10% Pump Spray belongs to a group of medicines called local anaesthetics.

It works by producing a temporary loss of sensation in the area where it is applied.

Your doctor, pharmacist or dentist will have explained what Xylocaine 10% Pump Spray is used for. Ask them if you want more information.

Xylocaine 10% Pump Spray is not addictive.

Before you use it

When you must not use it

Do not use Xylocaine 10% Pump Spray if you are pregnant or breastfeeding unless your doctor says it is safe. Ask your doctor about the risks and benefits involved.

There is no evidence available at the moment to show that being given Xylocaine 10% Pump Spray under your doctor's instructions is harmful to unborn babies.

Your baby can take in very small amounts of Xylocaine 10% Pump Spray from breast milk if you are breastfeeding, but it is unlikely that the amount available to the baby will do any harm.

Do not use Xylocaine 10% Pump Spray after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using Xylocaine 10% Pump Spray, talk to your pharmacist or doctor.

Before you start to use it

You must tell your doctor, pharmacist or dentist if:

you have any allergies to

- the active ingredient, lidocaine
- other local anaesthetics
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips tongue or other parts of the body
- rash, itching or hives on the skin

vou have any of these medical conditions

- epilepsy
- heart problems
- liver problems
- kidney problems
- open wounds or infection where the spray will be used
- porphyria (a rare metabolic disorder characterised by excessive levels of porphyrin in the blood and urine) Symptoms of acute porphyria include:
 - muscle pain or paralysis
 - seizures
 - disorientation
 - hallucination
 - bloody (red) urine
 - hypertension
 - abdominal pain
 - constipation - vomiting

It may not be safe for you to use Xylocaine 10% Pump Spray if you have any of these conditions.

Taking other medicines

Tell your doctor, pharmacist or dentist if you are taking any other medicines, including medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way Xylocaine 10% Pump Spray works.

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

If you have not told your doctor, pharmacist or dentist about any of these things, tell them before you use any Xylocaine 10% Pump

Using Xylocaine 10% Pump Spray

How to use it

Before using the spray, the bottle should be primed by pressing the piston once or twice. The dose depends on the size of the area and the procedure involved. Your healthcare

professional will use the dose that is suitable for you.

Each spray delivers 10 mg of lidocaine. The maximum dose is 20 sprays (200 mg).

In dentistry, the normal dose is 1-5 sprays. Two sprays per quarter of the mouth is recommended, with a maximum of 3 sprays per quarter of the mouth over 30 minutes.

In sinus procedures 3 sprays are used.

Up to 20 sprays may be necessary in childbirth and procedures of the throat and windpipe.

Lower doses are used for children aged 3-12 years. Xylocaine 10% Pump Spray is not recommended for children under 3 years.

Telephone your doctor, the Poisons Information Centre (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anybody else may have used too much Xylocaine 10% Pump Spray even if there are no signs of poisoning.

Symptoms of overdose include lightheadedness, drowsiness, dizziness and sometimes blurred vision. In the event of serious overdosage, trembling, seizures or unconsciousness may occur.

If you notice any of these signs, contact a doctor immediately.

While you are using it

Things to be careful of

Be careful driving or operating machinery after you have used Xylocaine 10% Pump Spray.

You may be drowsy and your reflexes may be slow.

Do not eat or drink anything for at least 1 hour after using Xylocaine 10% Pump Spray in the mouth or throat area.

You may swallow your food down the wrong way, or burn or bite your mouth.

Be careful not to spray Xylocaine 10% Pump Spray near the eyes.

If any of the spray does go in the eye, rinse immediately with lots of water for at least 15 minutes and call your doctor.

Talk to your doctor, pharmacist or dentist about these possibilities if you think they may bother you.

Side effects

Tell your doctor, pharmacist or dentist as soon as possible if you do not feel well while you are using Xylocaine 10% Pump

Xylocaine 10% Pump Spray will help to prevent pain and discomfort in most people, but it may have unwanted side-effects in a few people.

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, pharmacist or dentist to answer any questions you may have.

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

skin rash or irritation

· drowsiness

These are all mild side effects of Xylocaine 10% Pump Spray.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- · wheezing or difficulty breathing
- · chest pain
- · severe rash or itching
- · increased sweating
- · numbness

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

Serious side effects are rare.

Xylocaine 10% Pump Spray can pass into the bloodstream, and in high doses can rarely cause more serious side effects. These may include:

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

These are very serious side effects. You may need urgent medical attention or hospitalisation.

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

Some people may get other side effects while using Xylocaine 10% Pump Spray.

Storage

Keep Xylocaine 10% Pump Spray in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any spray you have left over if your doctor tells you to stop using it, or you find that the expiry date has passed.

Product description

Xylocaine 10% Pump Spray is a clear or almost clear slightly coloured liquid in a glass bottle closed by a spray head and pump assembly. Each spray contains lidocaine 10 mg as the active ingredient and the following inactive ingredients:

- ethanol
- macrogol 400
- banana flavour PHL-131980
- menthol
- saccharin
- purified water.

It is available in a pack size of $50\ mL$ which is sufficient for $500\ sprays$.

This pack also contains one short single use disposable nozzle. Additional short and long disposable nozzles are available separately. Nozzles should not be reused and should be discarded immediately after use. Do not use the same nozzle on different people.

Sponsor

Aspen Pharmacare Australia Pty Ltd 34-36 Chandos St St Leonards NSW 2065 Australia

Australian Registration Number:

AUST R 134540

This leaflet was revised in November 2024.