

2% Xylocaine® DENTAL with adrenaline (epinephrine) 1:80,000

Lidocaine (lignocaine) hydrochloride monohydrate
Adrenaline (epinephrine) acid tartrate

Consumer Medicine Information

What is in this leaflet

Xylocaine and **lidocaine** (also known as **lignocaine**), are different names for the same medicine - which is used as to stop pain during dental procedures. It is only called **Xylocaine Dental** in this leaflet.

This leaflet answers some of the common questions people ask about **Xylocaine Dental**. It does not contain all the information that is known about **Xylocaine Dental**.

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

All medicines have risks and benefits. Your dentist will have weighed the risks of you being given **Xylocaine Dental** against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your dentist or pharmacist.

Keep this leaflet.

You may need to read it again.

What XYLOCAINE DENTAL is for

Xylocaine Dental is used to prevent or relieve pain during dental procedures, but it will not put you to sleep.

Xylocaine Dental belongs to a group of medicines called local anaesthetics. It is injected into the mouth where it makes the nerves

unable to pass messages to the brain.

Depending on the amount used, **Xylocaine Dental** will either totally stop pain or will cause a partial loss of feeling.

Xylocaine Dental contains adrenaline (also known as epinephrine) to make it last longer. Adrenaline (epinephrine) makes the blood vessels at the site of injection narrower, which means you bleed less and it is easier for your dentist to see what is happening.

Your dentist will have explained why you are being treated with **Xylocaine Dental**. **Follow all directions given to you by your dentist carefully.** They may differ from the information contained in this leaflet. Ask your dentist if you want more information.

Xylocaine Dental is not addictive

Before you are given XYLOCAINE DENTAL

When you must not be given it

Do not use Xylocaine Dental if you are pregnant or breastfeeding unless your doctor and dentist say so. Ask your doctor or dentist about the risks and benefits involved.

Xylocaine Dental has been widely used during pregnancy and there have been no reports of any ill

effects on the baby. It can be used during childbirth.

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

Xylocaine Dental will only be used if the solution is clear, the package is undamaged and the use by (expiry) date marked on the pack has not been passed.

Before you are given it

You must tell your dentist if:

1. you have any allergies to

- other local anaesthetics
- any other substances
- ingredients listed at the end of this leaflet

If you have an allergic reaction, you may get a skin rash, hayfever, asthma or feel faint.

2. you have any of these medical conditions

- problems with your blood pressure or circulation
- blood poisoning
- problems with the clotting of your blood
- nerve problems
- heart problems
- liver problems
- kidney problems
- malignant hyperthermia

It may not be safe for you to be given **Xylocaine Dental** if you have any of these conditions.

Taking other medicines

Tell your dentist if you are taking any other medicines, including

- mexilitene
- medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way **Xylocaine Dental** works.

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

If you have not told your dentist about any of these things, tell them before you are given any **Xylocaine Dental**.

How XYLOCAINE DENTAL is given

Xylocaine Dental will be injected by your dentist into the gum inside your mouth near a single nerve, or into an area which contains a large number of nerves.

This will result in an area of numbness at the site or near the site of injection.

Xylocaine Dental should not be injected directly into the blood.

The dosage you will be given will depend on your body size, age and the type of dental work you will be having done.

Your dentist will have had a lot of experience injecting **Xylocaine Dental** or other local anaesthetics and will choose the best dose for you. They will be willing to discuss this decision with you.

Overdose

The dentist giving you Xylocaine Dental will be experienced in the use of local anaesthetics, so it is unlikely that you will be given an overdose.

However, if you are particularly sensitive to **Xylocaine Dental**, or the dose is accidentally injected directly into your blood, you may

develop problems for a short time. You may get a numb feeling in or around the mouth, feel dizzy or stiff, or have twitchy muscles. If **Xylocaine Dental** with adrenaline (epinephrine) is being used and this happens, you will feel alarmed and your heart will beat very rapidly.

Whenever you are given **Xylocaine Dental**, equipment will be available to care for you if an overdose happens.

While you are using it

Things you must not do

Do not eat or drink anything until the feeling has returned to your mouth.

You may burn or bite yourself.

Things to be careful of

Be careful driving or operating machinery until you know how Xylocaine Dental affects you.

You may be drowsy and your reflexes may be slow.

Do not drink alcohol immediately before or after you are given Xylocaine Dental.

If you drink alcohol while you are being given **Xylocaine Dental** your blood pressure may drop making you feel dizzy and faint.

Please talk to your dentist or pharmacist about these possibilities if you think they may bother you.

Side effects

Tell your dentist or pharmacist as soon as possible if you do not feel well while you are taking Xylocaine Dental.

Xylocaine Dental helps most people have pain free visits to the dentist, 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 dentist or pharmacist to answer any questions you may have.

Tell your dentist if you notice any of the following:

- nervousness
- dizziness
- blurred vision
- drowsiness
- ringing in the ears
- numbness
- feeling strange (disoriented)
- nausea
- vomiting

These are all mild side effects of **Xylocaine Dental**.

Tell your dentist immediately if you notice any of the following:

- feeling of alarm
- rapid heart beat (palpitations)

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

If **Xylocaine Dental** is given wrongly, or you are very sensitive to it, it sometimes causes

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

These are very serious side effects. If you have them, you may have had a serious (allergic) reaction to **Xylocaine Dental**. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

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

Some people may get other side effects while using **Xylocaine Dental**.

After using it

Storage

Xylocaine Dental will be stored by your dentist under the recommended conditions.

It should be kept in a fridge where the temperature stays at 2°C to 8°C (Refrigerate. Do not freeze) and it is protected from light.

Once removed from refrigeration for use, it will be stored below 25°C and used within 4 weeks and not returned to the refrigerator.

Excursions outside the recommended storage temperature are permitted during transport.

Disposal

Any Xylocaine Dental from a single dose which is not used, will be disposed of in a safe manner by your dentist.

Product description

Xylocaine Dental is a clear colourless solution and is available under the following name:

2% XYLOCAINE Dental with adrenaline (epinephrine) 1:80,000

The active ingredients are lidocaine (lignocaine) hydrochloride 20 mg/mL and adrenaline (epinephrine) 12.5 microgram/mL.

These are available as 2.2 mL dental cartridges in packs of 50 and 100 cartridges.

Not all pack sizes/presentations are being distributed.

Supplier/Sponsor

Xylocaine Dental is supplied in Australia by:

Dentsply Sirona Pty Ltd
11 – 21 Gilby Road
Mount Waverley, VIC 3149
Australia

Tel: 1300 55 29 29

Name and address of New Zealand Sponsor:

Dentsply Sirona (N.Z.) Limited
c/o- Lowndes Jordan
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This leaflet was prepared in February 2022.

Australian Registration Number
12024

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