

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

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Xylocaine DENTAL

The medicine, 2% Xylocaine DENTAL with adrenaline (epinephrine) 1:80,000, is hereafter referred to as Xylocaine DENTAL in this leaflet.

Xylocaine DENTAL contains the active ingredients lidocaine and adrenaline (epinephrine). It is used to prevent or relieve pain during dental procedures.

For more information, see Section [1. Why am I using Xylocaine DENTAL?](#) in the full CMI.

2. What should I know before I use Xylocaine DENTAL?

Do not use if you have ever had an allergic reaction to lidocaine, adrenaline or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Xylocaine DENTAL?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Xylocaine DENTAL and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How Xylocaine DENTAL is given?

Xylocaine DENTAL is injected by your dentist into the gum near nerves.

More instructions can be found in Section [4. How Xylocaine DENTAL is given?](#) in the full CMI.

5. What should I know while being given Xylocaine DENTAL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Xylocaine DENTAL.
Things you should not do	<ul style="list-style-type: none">• Do not eat or drink anything until the feeling has returned to your mouth. You may burn or bite yourself.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know Xylocaine DENTAL affects you. You may be drowsy and your reflexes may be slow.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol immediately before or after you are given Xylocaine DENTAL. Your blood pressure may drop making you feel dizzy and faint.
Looking after your medicine	<ul style="list-style-type: none">• Xylocaine DENTAL will be stored by your doctor or pharmacist under the recommended conditions.

For more information, see Section [5. What should I know while being given Xylocaine DENTAL?](#) in the full CMI.

6. Are there any side effects?

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Xylocaine DENTAL.

Some of these mild side effects include: nervousness, dizziness, blurred vision, drowsiness, ringing in ears, numbness, nausea and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

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

Active ingredients: *Lidocaine and adrenaline (epinephrine)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Xylocaine DENTAL with adrenaline (epinephrine) 1:80,000, hereafter referred to as Xylocaine DENTAL in this CMI.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Xylocaine DENTAL.

Where to find information in this leaflet:

- [1. Why am I using Xylocaine DENTAL?](#)
- [2. What should I know before I use Xylocaine DENTAL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How Xylocaine DENTAL is given?](#)
- [5. What should I know while being given Xylocaine DENTAL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Xylocaine DENTAL?

Xylocaine DENTAL contains the active ingredients lidocaine and adrenaline (epinephrine). Xylocaine DENTAL belongs to a group of medicines called local anaesthetics.

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

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.

The adrenaline (also known as epinephrine) makes 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.

2. What should I know before I use Xylocaine DENTAL?

Warnings

Do not use Xylocaine DENTAL if:

- you are allergic to lidocaine, adrenaline (epinephrine), or any of the ingredients listed at the end of this leaflet.
- the expiry date printed on the pack has passed.
- the solution is not clear, or the packaging is torn or shows signs of tampering.

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

Check with your doctor if you:

- have any other 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 (history or experience of a rapid rise in body temperature to a dangerously high level)

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant or breastfeeding, or planning to. Your dental practitioner can discuss with you 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.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Xylocaine DENTAL and affect how it works.

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

4. How Xylocaine DENTAL is given?

How much is given

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.

How it is given/administered

Xylocaine DENTAL will be injected by your dentist into the gum inside your mouth near a single nerve, or into an area that 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.

If you are given too much Xylocaine DENTAL

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.

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

If an overdose occurs, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

5. What should I know while being given Xylocaine DENTAL?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you have been recently given Xylocaine DENTAL.

Things you should not do

Do not eat or drink anything until the feeling has returned to your mouth. You may burn or bite yourself.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Xylocaine DENTAL affects you.

Xylocaine DENTAL may cause dizziness in some people. You may be drowsy and your reflexes may be slow.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

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.

When to discard your medicine

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Xylocaine DENTAL. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Xylocaine DENTAL will help relieve pain in most people, but it may have unwanted side effects.

If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> tremors nervousness dizziness blurred vision drowsiness ringing in the ears numbness feeling strange (disoriented) nausea vomiting. 	<p>Speak to your doctor if you have any of these mild side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>If Xylocaine DENTAL is given wrongly, or you are very sensitive to it, it sometimes causes</p> <ul style="list-style-type: none"> fits unconsciousness breathing problems low blood pressure collapse change in heart beat, slow or rapid heart beat (palpitations) feeling of alarm. 	<p>Call your doctor straight away, if you notice any of these serious side effects.</p> <p>You may need urgent medical attention or hospitalisation.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Xylocaine DENTAL contains

Active ingredients (main ingredients)	<ul style="list-style-type: none"> lidocaine hydrochloride monohydrate adrenaline (epinephrine) acid tartrate
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> sodium chloride sodium metabisulfite water for injections sodium hydroxide (for pH adjustment) hydrochloric acid (for pH adjustment)
Potential allergens	<ul style="list-style-type: none"> sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What Xylocaine DENTAL looks like

Xylocaine DENTAL is a clear, colourless, sterile solution for injection and is available as 2.2 mL dental cartridges in carton packs of 100 cartridges.

It contains the active ingredients: lidocaine hydrochloride 20 mg/mL and adrenaline (epinephrine) 12.5 microgram/mL.

Australian Registration Number: AUST R 12024

Who sponsors/distributes Xylocaine DENTAL

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