

ORAQIX® Periodontal Gel

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 ORAQIX?

ORAQIX periodontal gel is used to provide local anaesthesia in periodontal pockets during dental procedures. It contains lidocaine (lignocaine) and prilocaine, which belong to a group of medicines called local anaesthetics.

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

2. What should I know before I use ORAQIX?

Do not use if you have ever had an allergic reaction to ORAQIX 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 ORAQIX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ORAQIX and affect how it works.

Tell your doctor or dentist about all the medicines you take, including those bought without a prescription.

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

4. How ORAQIX is given?

ORAQIX is administered by a dental professional. It is applied directly into the periodontal pockets using a special applicator.

More instructions can be found in Section [4. How do I use ORAQIX?](#) in the full CMI.

5. What should I know while being given ORAQIX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you have been recently given ORAQIX.
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">• This medicine is not expected to affect your ability to drive a car or operate machinery.
Looking after your medicine	<ul style="list-style-type: none">• ORAQIX will be stored by your doctor or pharmacist under the recommended conditions.

For more information, see Section [5. What should I know while using ORAQIX?](#) 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 ORAQIX.

Common side effects may include irritation or numbness at the application site. Serious allergic reactions are rare but require immediate medical attention.

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.

ORAQIX® Periodontal Gel

Active ingredients: *lidocaine (lignocaine) and prilocaine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ORAQIX. 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 ORAQIX.

Where to find information in this leaflet:

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

1. Why am I using ORAQIX?

ORAQIX periodontal gel contains the active ingredients lidocaine (lignocaine) and prilocaine. ORAQIX belongs to a group of medicines called local anaesthetics.

This medicine is used in adults to stop or relieve pain during certain types of dental procedures, such as scaling, probing and root planing.

It is injected into the mouth, where it makes the nerves unable to pass messages to the brain. Depending on the amount used, ORAQIX will either totally stop pain or will cause a partial loss of feeling.

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

ORAQIX is not addictive.

Note, there is not enough information to recommend the use of this medicine for children and adolescents under the age of 18.

2. What should I know before I use ORAQIX?

Warnings

Do not use ORAQIX if:

- you are allergic to lidocaine (lignocaine), prilocaine, 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 experience:

- a 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.

Congenital or idiopathic methaemoglobinaemia

You must not be given ORAQIX if you have congenital or idiopathic methaemoglobinaemia.

A small amount of haemoglobin is normally present in the blood in a modified form called methaemoglobin.

Methaemoglobinaemia is a condition where an excess of haemoglobin has changed into methaemoglobin. If too much methaemoglobin is formed, it becomes more difficult for the blood to provide the tissue with oxygen.

Porphyria

You must not be given ORAQIX if you have porphyria that keeps going away and coming back.

Porphyrias are a group of conditions that affect the way your blood is made. Porphyrias may mean your blood is not as red as it should be. You may also have liver, skin or nerve problems.

Check with your doctor if you:

- have any other medical conditions
 - glucose-6-phosphatase dehydrogenase deficiencies
 - kidney or liver disease
 - irregular heart activity
 - mouth ulcers or an infection in your mouth

It may not be safe for you to be given ORAQIX 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.

ORAQIX should not be used in pregnancy unless clearly necessary.

You can continue to breast-feed after treatment with ORAQIX.

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 ORAQIX and affect how it works. These include:

- medicines used to treat irregular heart activity (antiarrhythmics)
- other medicines that can cause methaemoglobinaemia (e.g. certain kinds of antibiotics known as sulfonamides).

You may need different amounts of your medicines, or you may need to take different medicines.

Your dental practitioner and pharmacist have more information on medicines to be careful with or avoid while being given this medicine.

4. How ORAQIX is given?

Follow all directions given to you by your dental practitioner carefully. They may differ from the information contained in this leaflet.

How much is given

Your dental practitioner will give you ORAQIX. The dosage is decided by the dental practitioner and depends on how many and which teeth are to be treated.

The maximum dose in a single treatment is 5 cartridges.

How it is given/administered

The gel is applied inside the tooth pocket by the ORAQIX dispenser and a blunt-tipped applicator.

Note, ORAQIX is not injected.

The full effect is achieved after about half a minute and the dental practitioner can start further treatment.

You may receive other local anaesthetics at the same treatment session.

Frequent use of large amounts of ORAQIX is not recommended.

If you have the impression that the effect of ORAQIX is too strong or too weak, talk to your dental practitioner.

If you are given too much ORAQIX

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

However, if too much local anaesthetic (i.e. ORAQIX in combination with dental injection) has been given, the following side effects may occur: numbness of the lips and around the mouth, nervousness, light-headedness, dizziness, shakiness, or sometimes blurred vision, drowsiness and loss of consciousness. Other rare effects are fits, breathlessness and lowered blood pressure.

Tell your dental practitioner immediately if you have any of the above symptoms.

Too much prilocaine (ORAQIX in combination with dental injection) may also increase the methaemoglobin level and cause methaemoglobinaemia. Methaemoglobinaemia is characterised by slate-grey cyanosis, a bluish-grey discoloration of the lips and the skin. See additional information under Section [2. What should I know before I use ORAQIX?](#)

If you have any of the above symptoms, contact your dental practitioner or doctor, or go to Accident and Emergency at your nearest hospital for assessment of the risk and advice. You may need to be watched for several hours.

5. What should I know while using ORAQIX?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you have been recently given ORAQIX.
- If the gel comes into accidental contact with the eye, the eye must be washed with water immediately or saline solution and protected until you recover feeling in it.

Things you should not do

- ORAQIX may occasionally block all feeling in the treated area, so be careful to avoid accidental injury. Do not eat or drink anything until the feeling has returned to your mouth. You may burn or bite yourself.
- ORAQIX may interfere with tests for substances that sportswomen and sportsmen are banned from taking. ORAQIX may give a false positive test result for these substances

Driving or using machines

This medicine is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

ORAQIX will be stored by your dental practitioner under the recommended conditions.

It should be kept in a cool dry place where the temperature stays below 24°C.

When to discard your medicine

Any ORAQIX 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 ORAQIX. This medicine helps most people have pain free visits to the dental

practitioner, 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 attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your dental practitioner to answer any questions you may have.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • headache • tiredness • changes in taste sensation • pain, soreness, numbness, irritation, ulcers, blisters or abscess, redness or swelling in the mouth • throbbing or burning • feeling sick • 'flu'-like symptoms, including muscle aches or joint pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • skin rash • swelling (other than in the mouth) • fever • breathing difficulties • dizziness 	<p>Call your doctor as soon as possible, if you notice any of these serious side effects.</p> <p>You may need urgent medical attention.</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 ORAQIX contains

Active ingredients (main ingredients) (main ingredient)	<ul style="list-style-type: none"> • lidocaine (lignocaine) • prilocaine
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • poloxamer (containing butylated hydroxytoluene) • hydrochloric acid (for pH adjustment) • purified water

What ORAQIX looks like

ORAQIX is a liquid at room temperature and a gel at the temperature in the tooth pockets.

It is packed in dental cartridges intended for single use. Each cartridge contains 1.7 g gel containing the active ingredients: lidocaine (lignocaine) 42.5 mg and prilocaine 42.5 mg.

Australian Registration Number: AUST R 143855

New Zealand Registration Number: TT50-7897

Who sponsors/distributes ORAQIX

Australia

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