

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Oraqix.

It does not contain all of the information that is available. It does not take the place of talking to your dental practitioner.

All medicines have risks and benefits. Your dental practitioner has weighed the risks of you being given this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your dental practitioner.

Keep this leaflet. You may need to read it again.

What Oraqix is used for

Oraqix is a gel that is used for local anaesthesia in tooth pockets. It is used in adults to stop or relieve pain during certain types of dental procedures, such as scaling, probing and root planing.

Oraqix is only available from your dental practitioner.

This medicine belongs to a group of medicines called local anaesthetics.

It works by making 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.

Ask your dental practitioner if you have any questions about why this medicine has been prescribed for you.

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

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

Before you are given Oraqix

When you must not be given it

You must not be given Oraqix if you have an allergy to:

- any medicine containing lidocaine (lignocaine) and prilocaine
- any of the ingredients listed at the end of this leaflet
- any other similar medicines

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.

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.

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.

You will not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your dental practitioner.

Before you are given it

Tell your dental practitioner if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your dental practitioner if you have or have had any of the following medical conditions:

- glucose-6-phosphatase dehydrogenase deficiencies
- kidney or liver disease
- irregular heart activity
- mouth ulcers or an infection in your mouth

Tell your dental practitioner if you are pregnant or plan to become pregnant or are breast-feeding. 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.

If you have not told your dental practitioner about any of the above, tell him/her before you are given Oraqix.

Taking other medicines

Tell your dental practitioner if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Oraqix interfere with each other. These include:

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

These medicines may be affected by Oraqix or may affect how well it works. 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.

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.

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

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 (overdose)

The dental practitioner 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. (Methaemoglobinaemia is explained in the section "Before you are given it".)

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.

While you are using Oraqix

Things to be careful of

Caution must be exercised in the use of Oraqix gel. 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.

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.

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

Side effects

Tell your dental practitioner 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.

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

- 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

The above list includes the more common side effects of your medicine. They are usually mild and short lived.

Tell your doctor as soon as possible if you notice any of the following:

- skin rash
- swelling (other than in the mouth)
- fever
- breathing difficulties
- dizziness

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

Tell your dental practitioner or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given Oraqix

Storage

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.

Disposal

Any Oraqix from a single cartridge which is not used, will be disposed of in a safe manner by your dental practitioner.

Product Description

What it looks like

Oraqix is packed in dental cartridges intended for single use. Each cartridge contains 1.7 g gel.

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

Ingredients

Oraqix contains 42.5 mg lidocaine (lignocaine) and 42.5 mg prilocaine as the active ingredients.

It also contains:

- purified poloxamer 188 and 407 (including butylated hydroxytoluene)
- hydrochloric acid
- purified water

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Oraqix is supplied in Australia by:

Dentsply Sirona Pty Ltd
11-21 Gilby Road
MOUNT WAVERLEY VIC 3149
AUSTRALIA

Tel: 1300 55 29 29

Oraqix is supplied in New Zealand by:

Dentsply Sirona (N.Z.) Limited
c/o Lowndes Jordan
Level 15, PWC Tower
188 Quay Street
AUCKLAND 1010
NEW ZEALAND

Tel: 0800 33 68 77

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