

4% Articadent[®] DENTAL with adrenaline (epinephrine) 1:100,000

articaine hydrochloride with adrenaline (epinephrine)

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000. It does not contain all of the available information.

It does not take the place of talking to your dental practitioner.

All medicines have risks and benefits. Your dental practitioner has weighed the expected benefits of you using 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 against the risks this medicine could 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 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 is for

4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 are given by injection to cause loss of feeling before and during dental procedures. It contains two active ingredients: Articaine hydrochloride, a local anaesthetic to prevent the pain, and adrenaline (epinephrine) (as acid tartrate), a vasoconstrictor, which makes it last longer. Adrenaline

(epinephrine) narrows the blood vessels at the site of injection, which keeps the anaesthetic where it's needed for a longer time) and controls bleeding during the surgery.

4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 belongs to a group of medicines called local anaesthetics.

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

4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 is not addictive.

Before you take 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000

You must not take 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 if you have an allergy to:

- adrenaline (epinephrine) or articaine
- any of the ingredients listed toward the end of this leaflet (See "Ingredients")
- any other similar medicines, such as other local anaesthetics.

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.

4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 should not be used if any of the following apply to you:

- you are asthmatic or have broncho-spasmodic (difficulty in breathing) reactions to sulfites
- you have arterial hypertension (high blood pressure), coronary disease or valvular cardiac disease (heart or circulation problems)
- you have an overactive thyroid gland, whether or not treated for this
- you have cerebral arteriosclerosis (hardening in the brain arteries)
- you have an inflammation or infection in the region of the proposed injection
- you have diabetes
- children under the age of 4 years old.

This medicine will only be used if the package is undamaged and the use by date (expiry date) printed on the pack has not passed.

Tell your doctor if:

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

Tell your dental practitioner if you have or have had any of

the following medical conditions:

- problems with your heart, blood vessels or heart rhythm
- epilepsy
- hepatic (liver) problems
- renal (kidney) problems
- malignant hyperthermia (history or experience of a rapid rise in body temperature to a dangerously high level brought on by general anaesthesia)
- prostatic hypertrophy (enlarged prostate)
- you have any other medical conditions.

Tell your dental practitioner if you are taking any other medicines, including medicines you buy without a prescription.

Tell you 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.

If this medicine is used when you are breast-feeding you should not breast-feed for at least 48 hours following use of this medicine.

If you have not told your dental practitioner about any of the above, tell him/her before you are given 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000.

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 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 may interfere with each other. These include:

- Mono Amine Oxidase Inhibitors (MAOI) or tricyclic antidepressants (medicines used to treat depression), or have taken this type of medicine within the last two weeks.
- Phenothiazines (medicines used to treat mental illnesses).
- Vasopressor drugs (medicines used to elevate blood pressure)
- Ergot type oxytocic drugs (medicines used to induce labour in pregnant women).

4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 should be used with caution if you are taking the following medicines:

- Beta-blockers or guanethidine (medicines used to lower high blood pressure and/or treat heart problems)
- Hypoglycaemics (medicines used to treat irregular heartbeats)
- Antiepileptic drugs (medicines used to treat epilepsy)
- Cardiac glycosides (medicines used to treat heart failure)
- Cimetidine (medicine used to treat reflux and stomach or duodenal ulcers)
- Thyroid hormone
- Inhalational anaesthetics.

These medicines may be affected by 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 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 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 is given

Your dentist will explain to you why you are being treated with 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 and what dose you will be administered.

How it is given

Your dentist will inject 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 into your oral (mouth) cavity. This will result in an area of numbness at the site of the injection.

How much you are given

One cartridge is usually sufficient but your dentist may give you a greater quantity. He/she will adjust the dosage according to your age, your health, your weight and the dental work to be performed. If only a portion of a cartridge is used the remainder must be discarded.

4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 should not be injected directly into the blood.

If you are given too much (Overdose)

The dental practitioner giving you this medicine will be experienced in the use of local anaesthetics, so it is unlikely that you will be given an overdose.

However, some persons tolerate articaine and adrenaline (epinephrine) less well than others and the signs and symptoms of too much of these substances in your blood include:

- nervousness
- dizziness
- blurred vision nausea trembling convulsions
- slow or irregular heart beat
- troubled breathing.

Tell your dentist immediately if you experience any of these symptoms during or shortly after your treatment.

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

While you are taking 4% Articadent with adrenaline (epinephrine) 1:100,000

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 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 affects you.

This medicine may cause dizziness, nervousness, drowsiness, blurred vision or feeling strange/disoriented in some people and your reflexes may be slow. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Do not drink alcohol immediately before or after you are given 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000.

If you drink alcohol while you are being given 4% Articadent with adrenaline (epinephrine) 1:100,000, your blood pressure may drop, making you feel dizzy and faint.

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

What are the side effects?

Tell your dental practitioner as soon as possible if you do not feel well while you are being given 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000, even if the problem is not listed below.

This medicine helps most people have pain-free visits to the dental practitioner but like other medicines, 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

If you are over 65 years of age you may have an increased chance of getting 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 any of the below side effects occur.

The most commonly reported side effects are:

- infection and pain in the injection site
- tingling and numbness of the hand and feet or increased feeling or sensitivity of the skin
- feeling nervous, nauseous or dizzy
- headache
- trembling, buzzing in the ears, blurred vision or have any abnormal feeling
- difficulty breathing
- slow or irregular heart beat
- facial swelling or inflammation of gums
- skin rash, hives or itching
- loss of sensation and muscle function following injection of 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000. Resolution occurs generally within two weeks.

Very rare reactions

There are some serious unwanted reactions, which may happen if 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 is given into the veins or you are very sensitive to it, it may cause:

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

- collapse.

If experiencing any of these, you may have had a serious (allergic) reaction to 4% Articadent with adrenaline (epinephrine) 1:100,000. You may need urgent medical attention or hospitalisation.

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

You may be hypersensitive to sulfites and therefore show allergic symptoms to 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 such as breathing difficulties and/or skin reactions.

If you have problems with your blood vessels, circulation or have high blood pressure, you may react exaggeratedly to the vasoconstrictor contained in 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 and develop a small injury at the site of injection.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storage of 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000

It is most unlikely that you will be asked to look after this medicine. Your dentist will store this medicine below 25°C. He/she will not use this medicine after the expiry date printed on the package.

4% Articadent DENTAL with adrenaline (epinephrine)

1:100,000 must be stored in a cool, dry place where it stays below 25°C.

All medicines must be kept in a safe place out of the reach of children.

Product description

What 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 looks like

This medicine is packed in a carton containing 50, 2.2 mL glass cartridges.

Ingredients

4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 contains 40 mg/mL articaine hydrochloride and 0.01 mg/mL adrenaline (epinephrine) (as acid tartrate) as the active ingredients.

It also contains:

- Sodium chloride
- Sodium metabisulfite
- Sodium hydroxide and/or
- Hydrochloric acid solution
- Water for Injections.

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

Sponsor

4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000 is supplied by:

Australia

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

New Zealand

Dentsply Sirona (N.Z.) Limited
c/o Lowndes Jordan
Level 15, PWC Tower
188 Quay Street
Auckland 1010
New Zealand

Where to go for further information

Only a dentist can administer this product. Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. This leaflet provides only a summary of the information known about 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000. If you have any questions, want to know more about this medicine, or have some doubts, ask your dental practitioner or pharmacist.

This leaflet was prepared on 30 August 2018

The information provided applies only to 4% Articadent DENTAL with adrenaline (epinephrine) 1:100,000.

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