

DELTAZINE 1:100,000

Consumer Medicine Information

WHAT'S IN YOUR MEDICINE

Active ingredients

2.2 mL Cartridge:

Articaine hydrochloride 88.0 mg

Adrenaline (as acid tartrate) 22.0 µg

Active ingredients

1.7mL Cartridge:

Articaine hydrochloride 68.0 mg

Adrenaline (as acid tartrate) 17.0 µg

Other ingredients:

Sodium chloride, sodium metabisulfite, sodium hydroxide solution, water for injections.

Presentation:

Box of 50 cartridges single use, containing each 1.7 mL of solution

Box of 50 cartridges single use, containing each 2.2 mL of solution

WHAT IS YOUR MEDICINE USED FOR, AND HOW DOES IT WORK

DELTAZINE is 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 tartrate, a vasoconstrictor, which makes it last longer (adrenaline 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.

ADVICE BEFORE USING THE MEDICINAL PRODUCT

In deciding to use a medicine, the risks of using the medicine must be weighed against the good it will do. This is a decision you and your dentist will make before treatment.

This product should not be used if any of the following apply to you:

- You are allergic to adrenaline, articaine, or any local anaesthetic and any other ingredient included in the product.
- You are asthmatic or have broncho-spasmic (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.

You must tell your dentist if you have the following conditions:

- You have problems with your heart, blood vessels and heart rhythm.
- You have epilepsy.
- You have hepatic (liver) or renal (kidney) diseases.

- You have malignant hyperthermia (history or experience of a rapid rise in body temperature to a dangerously high level brought on by general anaesthesia).
- You have prostatic hypertrophy (enlarged prostate).
- You are pregnant or breast-feeding. If Deltazine is used when you are breast-feeding you should not breast-feed for at least 48 hours following use of Deltazine .
- You have any other medical conditions.

DELTAZINE MAY INTERACT WITH OTHER MEDICINES

It should not be used if you are taking:

- 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).

It should be used with caution if you are taking:

- Beta-blockers or guanethidine (medicines used to lower high blood pressure and/or treat heart problems).
- Hypoglycaemics (medicines used to treat high blood sugar).

- Anti-arrhythmic drugs and amiodarone (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.

Please make sure that you tell your dentist about all medicines which you are taking, whether prescribed or purchased over the counter.

HOW THIS MEDICINE WILL BE USED

Your dentist will explain to you why you are being treated with DELTAZINE and what dose you will be administered. Your dentist will inject Deltazine into your oral (mouth) cavity. This will result in an area of numbness at the site of the injection. One cartridge is usually sufficient but your dentist may give you a greater quantity. He 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.

While you are using DELTAZINE

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 DELTAZINE affects you. You may be drowsy and your reflexes may be slow.**
- **Do not drink alcohol immediately before or after you are given DELTAZINE .**

If you drink alcohol while you are being given DELTAZINE , 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

DELTAZINE like most other medicines may cause side effects in some patients. Although not all of these side effects may occur, if they do occur they may need medical attention. While you are in your dentist's office, your dentist will carefully follow the effects of DELTAZINE . However, some effects may not be noticed or appear later. Check with your dentist if any of the following side effects occur:

Common reactions:

- infection and pain in the injection site
- tingling and numbness of the hand and feet or increased feeling or sensitivity of the skin
- you are feeling nervous, nauseous or dizzy
- you have a headache
- you are trembling, have buzzing in the ears, blurred vision or have any abnormal feeling
- your breathing is difficult
- your heart is beating slowly or irregularly
- you have facial swelling or inflammation of gums
- you have skin rash, hives or itching

- you may have a loss of sensation and muscle function following the injection of DELTAZINE. Resolution occurs generally within two weeks.

Very rare reactions:

There are some serious unwanted reactions, which may happen if DELTAZINE 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 DELTAZINE . You may need urgent medical attention or hospitalisation.

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

Some people may get other side effects while using DELTAZINE .

You may be hypersensitive to sulfites and therefore show allergic symptoms to DELTAZINE 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 DELTAZINE and develop a small injury at the site of injection.

IN CASE OF OVERDOSE

Your dentist will determine the amount of solution, which is needed to provide pain control during your treatment, and it is very unlikely that you would receive too much DELTAZINE . However, some persons tolerate articaine and adrenaline 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.

STORAGE CONDITIONS

It is most unlikely that you will be asked to look after this medicine. Your dentist will keep it below 25°C and protected from light. He will not use this medicine after the expiry date printed on the package.

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

FURTHER INFORMATION

Only a dentist can administer this product. This leaflet provides only a summary of the information known about DELTAZINE . If you have any questions, want to know more about this medicine, or have some doubts, ask your dentist.

SPONSOR: Ato Zizine Pty Ltd, 14 Cliffbrook Crescent, Emu Plains, NSW 2750, Australia.

DATE OF INFORMATION: May, 2004

AUST R: 101551 (50 cartridges of 1.7 mL)

AUST R: 101552 (50 cartridges of 2.2 mL)

DELTAZINE 1:100,000

(Articaine hydrochloride 4% with adrenaline 1:100 000, solution for injection)