

SEPTANEST 1:200,000 and SEPTANEST 1:100,000

Articaine hydrochloride and adrenaline

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

Please read this leaflet carefully before you use SEPTANEST 1:200,000 or SEPTANEST 1:100,000.

This leaflet answers some common questions about SEPTANEST 1:200,000 or SEPTANEST 1:100,000. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking SEPTANEST 1:200,000 or SEPTANEST 1:100,000 against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT IS SEPTANEST 1:200,000 and SEPTANEST 1:100,000 USED FOR

SEPTANEST 1:200,000 and SEPTANEST 1:100,000 contain the active ingredients: Articaine hydrochloride, a local anaesthetic to prevent the pain, and adrenaline, 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.

SEPTANEST 1:200,000 and SEPTANEST 1:100,000 belong to a group of medicines called local anaesthetics. SEPTANEST 1:200,000 or SEPTANEST 1:100,000 is injected into the mouth where it makes the nerves unable to pass messages to the brain.

Your dentist will have explained why you are being given SEPTANEST 1:200,000 or SEPTANEST 1:100,000.

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.

SEPTANEST 1:200,000 and SEPTANEST 1:100,000 are not addictive.

BEFORE YOU ARE GIVEN SEPTANEST 1:200,000 OR SEPTANEST 1:100,000

When you must not be given SEPTANEST 1:200,000 or SEPTANEST 1:100,000

- if you are allergic to articaine or adrenaline or sodium

metabisulfite or any of the other ingredients of this medicine;

- if you are allergic to other local anaesthetics;
- if you lack a natural chemical substance called cholinesterase in your blood (plasma cholinesterase deficiency);
- if your thyroid is severely overfunctioning (thyrotoxicosis);
- if you have a tumor called pheochromocytoma;
- if you suffer from severe heartbeat coordination problems (cardiac disorders, atrioventricular block);
- **Children under the age of 4 years old.**

Before you are given SEPTANEST 1:200,000 OR SEPTANEST 1:100,000:

Tell your dentist:

- if you have low or high blood pressure;
- if you have heart failure;
- if you have ischemic heart disease;
- if you recently had a heart attack (myocardial infarction);
- if you recently had coronary artery bypass surgery;
- if you have fast irregular heartbeat (tachyarrhythmia);
- if you have problems with your blood vessels (e.g. narrowing and hardening of the arteries that supply the legs and feet);
- if you are epileptic;

- if you have problems with your liver;
- if you have problems with your kidney;
- if you suffer from a disease called Myasthenia Gravis causing weakness in the muscles;
- if you suffer from a condition called Porphyria which causes either neurological complications or skin problems;
- if you have diabetes;
- if you have cerebrovascular insufficiency (obstruction of one or more arteries that supply blood to the brain)
- if you suffer from a disease called angle-closure glaucoma which affects your eyes;
- if you have inflammation or infection in the area to be injected
- if you are more than 70 years old.
- **If you are pregnant or breast-feeding.** If SEPTANEST 1:200,000 OR SEPTANEST 1:100,000 is used when you are breast-feeding you should not breast-feed for at least 4 hours following use of SEPTANEST 1:200,000 OR SEPTANEST 1:100,000.
- You have any other medical conditions.

Taking other medicines

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

Your dentist should take special attention if you are taking the following medicines:

- other local anesthetics, medicines that cause reversible loss of sensation (including volatile anaesthetics such as halothane);
- sedatives (such as benzodiazepine, opioids);

- neuroleptic drugs (for example phenothiazines)
- heart and blood pressure medicines
- tricyclic antidepressants used to treat depression (such as amitriptyline, desipramine, imipramine, nortriptyline and protriptyline)
- Mono Amine Oxidase Inhibitors (MAOI) or have taken this type of medicine within the last two weeks.
- COMT-inhibitors to treat Parkinson's disease (such as entacapone) medicines used to treat irregular heartbeats (for example digitalis, quinidine)
- Cimetidine (medicine used to treat reflux and stomach or duodenal ulcers).
- Thyroid hormone
- medicines used for migraine attacks (such as methysergide or ergotamine)
- medications preventing blood clotting (antiplatelets, anticoagulants)
- sympathomimetic vasopressor such as oxymetazoline used to treat swelling or inflammation of the nose
If sympathomimetic vasopressor such as cocaine, amphetamines, phenylephrine, pseudoephedrine, oxymetazoline have been used within the past 24 hours, the planned dental treatment has to be postponed.

HOW SEPTANEST 1:200,000 AND SEPTANEST 1:100,000 IS GIVEN?

SEPTANEST 1:200,000 and SEPTANEST 1:100,000 are given by injection to cause loss of feeling before and during dental procedures.

Your dentist will explain to you why you are being treated with SEPTANEST 1:200,000 or

SEPTANEST 1:100,000 and what dose you will be administered.

Your dentist will inject SEPTANEST 1:200,000 or SEPTANEST 1:100,000 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.

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

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 heartbeat, troubled breathing.

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

WHILE YOU ARE USING SEPTANEST 1:200,000 OR SEPTANEST 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

it affects you. You may be drowsy and your reflexes may be slow.

- Do not drink alcohol immediately before or after you are given it.
- If you drink alcohol while you are being given it, 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

Tell your dentist as soon as possible if you do not feel well when using SEPTANEST 1:200,000 or SEPTANEST 1:100,000.

All 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 SEPTANEST 1:200,000 or SEPTANEST 1:100,000. However, some effects may not be noticed or appear later.

Tell your dentist if you notice any of the following serious side effects:

- Swollen face, tongue or pharynx, difficulty to swallow, hives or difficulties to breath
- Rash, itching, swelling of the throat and difficulty breathing: this might be symptoms of an allergic (hypersensitivity) reaction.
- Horner's syndrome – a combination of drooping of the eyelid and constriction of the pupil
- These side effects happen rarely (may affect up to 1 in 1,000 people).

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

Common side effects: may affect up to 1 in 10 people:

- abnormal rapid heartbeat
- abnormal slow heartbeat
- low blood pressure
- swelling of tongue, lips and gums, inflammation of gums, numbness of your tongue mouth and lips
- numbness or reduced sense of touch in and around the mouth
- metallic taste, taste disturbance or loss of taste function
- increased, unpleasant or abnormal sense of touch
- neuropathic pain – pain due to nerve damage
- increased sensitivity to heat
- headache
- presyncope - syncope
- dizziness
- pallor

Uncommon side effects: may affect up to 1 in 100 people:

- burning sensation
- high blood pressure
- inflammation of the tongue and mouth
- nausea, vomiting, diarrhea
- rash, itching
- pain in the neck or at the site of the injection
- pain

Rare side effects: may affect up to 1 in 1,000 people:

- wheezing (bronchospasm), asthma
- hives (urticarial)
- nervousness, anxiety
- somnolence
- facial nerve disorder (paralysis)
- involuntary eye movement
- double vision, temporary blindness
- drooping or falling of the upper or lower eyelid, constriction of the pupil
- the posterior displacement of the eyeball within the orbit due to changes in the volume of the orbit – called Enophthalmos

- ringing of the ears, over-sensitivity of hearing
- palpitations
- hot flush
- difficulty breathing
- exfoliation and ulceration of the gums
- muscle twitch, involuntary muscle contraction
- chills
- exfoliation of the injection site
- fatigue, weakness
- convulsions
- loss of consciousness
- coma
- speech disorder
- balance disorder
- vertigo

Very rare side effects: may affect up to 1 in 10,000 people:

- persistent loss of sensitivity, extended numbness and loss of taste
- accidental injury
- muscle spasms

Not known: frequency cannot be estimated from the available data

- extremely good mood (euphoria)
- heartbeat coordination problems (conduction disorders, atrioventricular block)
- widening or narrowing of blood vessels
- hoarseness
- difficulty in swallowing
- redness of the skin (erythema)
- worsening of the neuromuscular symptoms in Kearns-Sayre syndrome
- local swelling
- abnormally increased sweating, feeling hot or feeling cold
- post-operative swelling
- malaise

If experiencing any of these, you may have had a serious (allergic) reaction to SEPTANEST 1:200,000 OR SEPTANEST 1:100,000. You may need urgent medical attention or hospitalization.

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

Some people may get other side effects while using SEPTANEST 1:200,000 or SEPTANEST 1:100,000.

AFTER USING SEPTANEST 1:200,000 AND SEPTANEST 1:100,000

Storage

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

SEPTANEST 1:200,000 and SEPTANEST 1:100,000 will be stored by your dentist under recommended conditions. The medicine should be stored below 25°C. Protect from Light. Do not freeze.

PRODUCT DESCRIPTION

What it looks like

Solution is clear, not opalescent and colorless.

Active Ingredients

SEPTANEST 1:200,000 contains 40 mg/ml of Articaine hydrochloride and 0.005 mg/ml of Adrenaline.

SEPTANEST 1:100,000 contains 40 mg/ml of Articaine hydrochloride and 0.010 mg/ml of Adrenaline.

Other Ingredients

Sodium chloride, sodium metabisulfite, sodium hydroxide and water for injections

FURTHER INFORMATION

Only a dentist can administer this product. This leaflet provides only a summary of the information known about SEPTANEST 1:200,000 and SEPTANEST 1:100,000. If you have any questions, want to know more about this medicine, or have some doubts, ask your dentist.

SPONSOR

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REGISTRATION NUMBERS

Septanest 1:100,000 AUST R
101544 (50 cartridges of 1.7mL)

Septanest 1:100,000 AUST R
101545 (50 cartridges of 2.2 mL)

Septanest 1:200,000 AUST R
261413 (50 cartridges of 1.7mL)

Septanest 1:200,000 AUST R
271232 (50 cartridges of 2.2 mL)

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