



Septanest 1:100,000 Septanest 1:200,000

Solution for injection
Articaine hydrochloride and adrenaline

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your dentist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your dentist.

In this leaflet:

1. What SEPTANEST is and what it is used for
2. Before you use SEPTANEST
3. How to use SEPTANEST
4. Possible side effects
5. How to store SEPTANEST
6. Further information

1. What SEPTANEST is and what it is used for

SEPTANEST is given by injection to cause loss of feeling before and during dental procedures.

It contains two active ingredients:

- articaine hydrochloride, a local anaesthetic which prevents pain,
- and adrenaline tartrate, a vasoconstrictor which makes the effect last longer. Adrenaline narrows the blood vessels at the site of injection, which keeps the anaesthetic where needed for a longer time. It also controls the bleeding during the surgery.

Depending on the kind of dental procedure performed, your dentist will choose:

- SEPTANEST 1:200,000 is usually used for simple and short dental procedure or
- SEPTANEST 1:100,000 is more adapted to procedures lasting longer or with possible significant bleeding.

SEPTANEST is for children over 4 years old and adults.

Only a dentist can administer this product.

2. Before you use SEPTANEST

Do not use SEPTANEST

- if you are allergic (hypersensitive) to one of the active ingredients (articaine hydrochloride or adrenaline tartrate) or to any of the other ingredients (refer to section 6)

- if you are allergic to local anaesthetics
- if you are asthmatic or have suffered difficulty with your breathing as a result of taking medicines which contain ingredients called sulphites or metabisulphites
- if you have problems in the way your muscles work by not having enough of a substance called cholinesterase in your body
- if you are taking or have taken medicines for depression in the last two weeks
- in children under 4 years old

Take special care with SEPTANEST

Before receiving this medicine, tell your dentist if:

- you have problems with your heart, your blood vessels or your heart rhythm
- you have problems with your liver
- you are epileptic
- you have diabetes
- you have an overactive thyroid gland

If you have problems with the blood supply to your arms and/or legs or high blood pressure this medicine may result in a small injury at the site of injection.

Patients who already have a condition of the blood called methaemoglobinaemia may find they become worse.

Using other medicines

Please tell your dentist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- Do not use SEPTANEST if you are taking or have taken medicines for depression in the last two weeks.

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

- medicines used to reduce your blood pressure (e.g. betablockers like propranolol or vasopressor drugs like dihydroergotamine)
- medicines used to treat irregular heartbeats (e.g. cardiac glycosides like digoxin)

Pregnancy

This medicine should be used with caution during pregnancy. Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

You should not breast-feed for 48 hours following the use of SEPTANEST.

Driving and using machines

If you experience side effects, including dizziness or blurred vision, you should not drive or operate machinery until these effects have disappeared.

Important information about some ingredients of SEPTANEST

SEPTANEST contains

- less than 1 mmol (23mg) sodium per cartridge, i.e. essentially "sodium free".



- sodium metabisulphite: it may rarely cause severe allergic reactions and difficulty in breathing (bronchospasm).



3. How to use SEPTANEST

Your dentist will explain to you why you are being treated with SEPTANEST. He or she will choose the formula and adjust the dosage according to your age, your health and the dental procedure. One cartridge is usually sufficient but your dentist may give you a greater quantity. SEPTANEST is injected between two teeth.

If your dentist uses more SEPTANEST than he or she should

If you think you may have been given too much of this injection and feel unwell (see section 4, possible side effects), tell your dentist.

4. Possible side effects

Like all medicine, SEPTANEST can cause side effects although not everybody gets them. While you are in your dentist's office, your dentist will carefully follow the effects of SEPTANEST.

Allergic (hypersensitivity) reactions may occur when using this medicine. Symptoms of these reactions might include: rash, itching, swelling of the throat and difficulty breathing. Inform your dentist, doctor or pharmacist immediately if one of these effects applies to you.

Administration of SEPTANEST may cause the following side effects, which require rapid corrective measures to prevent possible worsening:

- Effects on your heart and blood vessels: slow heartbeats, drop in blood pressure.
- Effects on your lung: slow or fast breathing which could lead to temporarily stopping breathing.
- Effects on your senses: trembling, shaking, uncontrolled eye movement, buzzing in the ears, problems with speech, yawning.
- General effects: headache, nausea, feeling nervous, apprehension.
Inform your dentist, doctor or pharmacist immediately if one of these effects applies to you.

The following common side effects affect between 1 and 10 of every 100 patients treated:

- Effects on your senses: loss of sensation and muscle function following the injection of SEPTANEST. Resolution occurs generally within eight weeks.
- Effects on your skin: facial swelling or inflammation of gums.
- General effects: headache

The following uncommon side effects affect less than 1 of every 100 patients treated:

- General effects: nausea

The following very rare side effects affect 1 of 10,000 patients treated:

- Severe allergic reaction including swelling of the face, lips and/or tongue, difficulty breathing.
- Allergic reactions including skin rash, hives or itching.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your dentist, doctor or pharmacist

5. How to store SEPTANEST

Keep out of the reach and sight of children.

It is most unlikely that you will be asked to look after this medicine.

Your dentist will not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

Your dentist will keep it up to 25° C, stored in the original container (protected from light). It should not be frozen.

Before giving you SEPTANEST, your dentist will check if its colour is not pinkish or darker than slightly yellow or if it does not contain a precipitate.

6. Further information

What SEPTANEST contains

- Active substances: each ml of solution for injection contains 40 mg of articaine hydrochloride and
 - 18.2 micrograms of adrenaline (epinephrine) for SEPTANEST 1:100,000.
 - 9.1 micrograms of adrenaline (epinephrine) for SEPTANEST 1:200,000.
- The other ingredients are: sodium metabisulphite, sodium chloride, sodium hydroxide and water for injections.

What SEPTANEST looks like and content of the pack

It is a clear and colourless solution. SEPTANEST is available in boxes containing 50 cartridges of 1.7 ml or of 2.2 ml.

Marketing authorisation holder:

Septodont Ltd, Units R & S
Orchard Business Centre - St Barnabas Close
Allington, Maidstone - Kent ME16 0JZ - UK

Manufacturer:

Septodont
58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés - France

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If more PILs are necessary, call free number
0800435155.

SEPTODONT

58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés - France

