

005061459300

Septanest 1:100,000

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

Septanest 1:200,000

Articaine hydrochloride 4% with adrenaline (epinephrine) injection 1:200,000

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you start using this medicine. It tells you the important points you should know about SEPTANEST.

Pharmaceutical form

Solution for injection

What's in your medicine

Each ml of solution for injection contains 40.00 mg of articaine hydrochloride and

- 18.2 micrograms of adrenaline (epinephrine) as the acid tartrate (10.00 micrograms expressed as base) for SEPTANEST 1:100,000.
- 9.1 micrograms of adrenaline (epinephrine) as the acid tartrate (5.00 micrograms expressed as base) for SEPTANEST 1:200,000.

It is a clear and colourless solution.

It also includes the following inactive ingredients: sodium metabisulphite, sodium chloride, sodium hydroxide and water for injections.

SEPTANEST is available in boxes containing 50 cartridges of 1.7 ml or of 2.2 ml.

Name of marketing authorisation holder: Septodont UK Ltd, Units R & S - Orchard Business Centre - St Barnabas Close -Allington, Maidstone, Kent ME16 0JZ - UK

Name of manufacturer: Septodont, 58 rue du Pont de Créteil, 94100 Saint-Maur-des-Fossés, France.

About your medicine

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) and controls the bleeding during the surgery.

Before this medicine is used

SEPTANEST is not for use in children of less than 4 years.

SEPTANEST contains sodium metabisulphite (E 223). Sodium metabisulphite can cause allergic-type reactions including anaphylactic symptoms and bronchospasm (difficulty in breathing) in some people. If you suffer from allergy or asthma this is more likely to happen.

Before receiving this medicine, tell your dentist if:

- you are allergic to local anaesthetics or any particular ingredients,
- you are asthmatic or have suffered difficulty with your breathing as a result of taking medicines which contain ingredients called sulphites or metabisulphites,
- you are taking antidepressant treatment or have taken such a drug within the two last weeks,
- you have problems in the way your muscles work by not having enough of a substance called cholinesterase in your body,
- you have problems with your heart, your blood vessels, your heart rhythm or your liver,
- you are epileptic,
- you are pregnant or breast-feeding,
- you have diabetes or have an overactive thyroid gland, whether or not treated for this.

There are medicines which should not be given with SEPTANEST or which should be used with caution as β -blocking agents (e.g. propranolol), cardiac glycosides (e.g. digoxin) and vasopressor drugs (e.g. dihydroergotamine). Please make sure that you tell your dentist about all medicines which you are taking, whether prescribed or purchased.

Driving or operating machinery

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

How this medicine will be used

Your dentist will explain to you why you are being treated with SEPTANEST and tell you which formula and what dose you will be administered. One cartridge is usually sufficient but your dentist may give you a greater quantity. He chooses the formula and adjusts the dosage according to your age, to your health and to the dental work. SEPTANEST 1:200,000 is usually used for simple and short dental works. SEPTANEST 1:100,000 is more adapted to procedures lasting longer or with possible significant bleeding.

What to do if an overdose is taken

If you think you may have been given too much of this injection and feel unwell, tell your dentist.

Unwanted effects

SEPTANEST 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 office, your dentist will carefully follow the effects of SEPTANEST. However, some effects may not be noticed or appear later. Check with your dentist, doctor or pharmacist if any of the following side effects occur :

- you are feeling nervous, nauseous or dizzy,
- you have headache,
- you are trembling, have buzzing in the ears, blurred vision or have any abnormal feeling, yawning, problems with speech, shaking,
- 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 or severe allergic reaction,
- you may have a loss of sensation and muscle function following the injection of SEPTANEST. Resolution occurs generally within eight weeks.

You may be hypersensitive to sulphites and therefore show allergic symptoms to SEPTANEST as respiratory or skin reactions.

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.

Warning

Your dentist will not use this medicine if its colour is pinkish or darker than slightly yellow or if it contains a precipitate.

SEPTANEST 1:100,000 and 1:200,000 contain less than 1 mmol sodium (0.058 mmol/ 1.7 ml or 0.075 mmol/ 2.2 ml), i.e. essentially "sodium free".

Storing your medicine

It is most unlikely that you will be asked to look after this medicine. Your dentist will keep it up to 25° C, stored in the original container (protected from light). It should not be frozen. 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

Remember this medicine is only for you. Only a dentist can administer this product.

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

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If more PILs are necessary, call free number 0800 435155.

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