PACKAGE LEAFLET

Package leaflet: Information for the user

Septanest 1:100,000
Septanest 1:200,000
Solution for injection
articaine hydrochloride / adrenaline

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your dentist, doctor or pharmacist.
- If you get any side effects, talk to your dentist, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Septanest is and what it is used for
2. What you need to know before you are given Septanest
3. How to use Septanest
4. Possible side effects
5. How to store Septanest
6. Contents of the pack and other information

1. What Septanest is and what it is used for

Septanest is used to numb (anaesthetise) your oral cavity during dental procedures.
This medicine contains two active substances:
- articaine, a local anaesthetic which prevents pain, and
- adrenaline, a vasoconstrictor which narrows the blood vessels at the site of injection, and thereby prolongs the effect of articaine. It also decreases bleeding during surgery.

You will be given Septanest by a dentist.
Septanest is for children over 4 years of age (ca. 20 kg in body weight), adolescents and adults.

Depending on the kind of dental procedure performed, the dentist will choose between the two medicines:
- Septanest 1:200,000 is usually used for simple and short dental procedures
- Septanest 1:100,000 is more adapted to procedures lasting longer or with possible significant bleeding.

2. What you need to know before you are given Septanest

Do not use Septanest if you suffer from any of the following conditions:
- allergy to articaine or adrenaline or any of the other ingredients of these medicines (listed in section 6);
- allergy to other local anaesthetics;
- epilepsy, not adequately controlled by drug treatment.

Warnings and precautions
Talk to your dentist before using Septanest if you suffer from any of the following conditions:
- severe heart rhythm disorders (e.g. second and third-degree AV block);
- acute heart failure (acute heart weakness, e.g. unexpected chest pain while resting or after

myocardial infraction (e.g. heart attack));
- low blood pressure;
- abnormal rapid heartbeats;
- heart attack in the last 3 to 6 months;
- coronary artery bypass surgery in the last 3 months;
- taking some medicines for blood pressure called beta blockers, such as propranolol. There is the danger of a hypertensive crisis (very high blood pressure) or severe slowing of the pulse (see section other medicines);
- very high blood pressure;
- simultaneously taking some medicines for the treatment of depression and Parkinson's disease (tricyclic antidepressants). These medicines may intensify the effects of adrenaline.
- epilepsy;
- lacking of a natural chemical substance called cholinesterase in your blood (plasma cholinesterase deficiency);
- problems with your kidneys;
- serious problems with your liver
- a disease called *Myasthenia Gravis* causing weakness in the muscles*;*
- *Porphyria* which causes either neurological complications or skin problems*;*
- use other local anaesthetics, medicines that cause reversible loss of sensation (including volatile anaesthetics such as halothane);
- taking medications called antiplatelets or anticoagulants, to prevent narrowing or hardening of your blood vessels in the arms and legs;
- are more than 70 years old.
- have or have had any heart problem
- have uncontrolled diabetes;
- severely overfunctioning thyroid (thyrotoxicosis);
- tumour called pheochromocytoma;
- a disease called angle-closure glaucoma which affects your eyes;
- inflammation or infection in the area to be injected.
- decreased amounts of oxygen in the body's tissues (hypoxia), high blood potassium (hyperkalaemia) and metabolic disorders as a result of too much acid in the blood (metabolic acidosis).

Other medicines and Septanest

Tell your dentist if you are taking, have recently taken or might take any other medicines.
It is especially important to tell your dentist if you are taking any of the following medicines:
- other local anaesthetics, medicines that cause reversible loss of sensation (including volatile anaesthetics such as halothane);
- sedatives (such as benzodiazepine, opioids), for example to reduce your apprehension before the dental procedure;
- heart and blood pressure medicines (such as guanadrel, guanethidine, propranolol, nadolol,)
- tricyclic antidepressants used to treat depression (such as amitriptyline, desipramine, imipramine, nortriptyline, maprotiline and protriptyline);
- COMT-inhibitors to treat Parkinson's disease (such as entacapone or tolcapone);
- MAO inhibitors used to treat depressive or anxiety disorders (such as moclobemide, phenelzine, tranylcypromine, linezolide);
- medicines used to treat irregular heartbeats (for example digitalis, quinidine);
- medicines used for migraine attacks (such as methysergide or ergotamine);
- sympathomimetic vasopressors (such as cocaine, amphetamines, phenylephrine, pseudoephedrine, oxymetazoline), used to raise the blood pressure: if used within the past 24 hours, the planned dental treatment has to be postponed.
- neuroleptic drugs (for example phenothiazines).

Septanest with food
Avoid eating, included chewing-gum, until normal sensation is restored because there is a risk that you may bite your lips, cheeks or tongue, especially in children.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your dentist or doctor for advice before using this medicine.

Your dentist or doctor will decide if you can use Septanest 1:100,000 or Septanest 1:200,000 during pregnancy.

Breast-feeding can be resumed after 5 hours following anaesthesia.
No adverse effects on fertility are anticipated at doses used for a dental procedure.

Driving and using machines
If you experience side effects, including dizziness blurred vision or fatigue, you should not drive or operate machinery until you recover your abilities (generally within 30 minutes following the dental procedure).

Septanest contains sodium and sodium metabisulfite.
- Sodium: this medicine contains less than 1 mmol sodium (23 mg) per cartridge, that is to say essentially 'sodium-free'.
- Sodium metabisulfite: it may rarely cause severe allergic reactions and breathing difficulties (bronchospasm).

If there is any risk of an allergic reaction, your dentist will choose a different medicine for anesthesia.

3. How to use Septanest

Only physicians or dentists are trained to use Septanest.
Your dentist will choose between Septanest 1:100,000 and Septanest 1:200,000, and determine the appropriate dose taking into account your age, your weight, your general health and the dental procedure.
The lowest dose leading to effective anaesthesia should be used.

This medicine is given by a slow injection in the oral cavity.

If you are given more Septanest than you should
It is not likely that you will be given too much of this injection but if you should begin to feel unwell, tell your dentist. Symptoms of overdose include severe weakness, paleness of the skin, headache, feeling agitated or restless, feeling disorientated, losing your balance, involuntary trembling or quivering, dilation of the pupil, blurred vision, problems clearly focusing an object, speech disorders, dizziness, convulsions, stupor, loss of consciousness, coma, yawning, abnormally slow or rapid breathing which could lead to temporarily stopping breathing, failure of the heart to contract effectively (called cardiac arrest).

If you have any further questions on the use of this medicine, ask your dentist.

4. Possible side effects

Like all medicines, this medicine 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.

Inform your dentist, doctor or pharmacist <u>immediately</u> if you experience one of the following serious side effects:

- swollen face, tongue or pharynx, difficulty to swallow, hives or difficulties to breath (angioedema)
- rash, itching, swelling of the throat and difficulty breathing: this might be symptoms of an allergic (hypersensitivity) reaction.
- a combination of drooping of the eyelid and constriction of the pupil (Horner's syndrome)

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:

- inflammation of the gums
- neuropathic pain – pain due to nerve damage
- 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
- increased sensitivity to heat
- headache
- abnormal rapid heartbeat
- abnormal slow heartbeat
- low blood pressure
- swelling of tongue, lips and gums

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

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

- nervousness, anxiety
- facial nerve disorder (facial palsy)
- somnolence
- involuntary eye movement
- double vision, temporary blindness
- drooping of the eyelid, and constriction of the pupil (Horner’s syndrome)
- recession displacement of the eyeball into the orbit (*Enophthalmos)*
- ringing of the ears, over-sensitivity of hearing
- palpitations
- hot flush
- wheezing (bronchospasm), asthma
- difficulty breathing
- exfoliation and ulceration of the gums
- exfoliation of the injection site
- hives (urticarial)
- muscle twitch, involuntary muscle contraction
- fatigue, weakness
- chills

Very rare side effects: may affect up to 1 in 10,000 people:
- persistent loss of sensitivity, extended numbness and loss of taste

Not known: frequency cannot be estimated from the available data
- extremely good mood (euphoria)
- heartbeat coordination problems (conduction disorders, atrioventricular block)
- increased amount of blood in a part of the body leading to congestion of blood vessels
- widening or narrowing of blood vessels
- hoarseness
- difficulty in swallowing
- swelling of cheeks and local swelling
- burning mouth syndrome
- redness of the skin (erythema)
- abnormally increased sweating,
- worsening of the neuromuscular symptoms in Kearns-Sayre syndrome
- feeling hot or feeling cold
- lock-jaw

Reporting of side effects
If you get any side effects, talk to your dentist, doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of these medicines.

5. How to store Septanest

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.
Do not freeze.
Keep the cartridges in the tightly closed outer carton in order to protect from light.

Do not use this medicine if you notice that the solution is cloudy or discoloured.

The cartridges are intended for single use. Use immediately after the opening of the cartridge. Unused solution must be discarded.

Do not throw away any medicines via wastewater or household waste. Your dentist knows how to throw away medicines no longer used. These measures will help protect the environment.

6. Contents of the pack and other information

What Septanest contains
- The active substances are articaine hydrochloride and adrenaline tartrate.
  - Each cartridge of 1.7 ml of solution for injection of Septanest 1:200,000 contains 68 mg of articaine hydrochloride and 8.50 micrograms of adrenaline (as adrenaline tartrate).
  - Each cartridge of 2.2 ml of solution for injection of Septanest 1:200,000 contains 88 mg of articaine hydrochloride and 11 micrograms of adrenaline (as adrenaline tartrate).

- 1 ml of Septanest 1:200,000 contains 40 mg of articaine hydrochloride and 5 micrograms of adrenaline (as adrenaline tartrate).

- Each cartridge of 1.7 ml of solution for injection of Septanest 1:100,000 contains 68 mg of articaine hydrochloride and 17 micrograms of adrenaline (as tartrate).
- Each cartridge of 2.2 ml of solution for injection of Septanest 1:100,000 contains 88 mg of articaine hydrochloride and 22 micrograms of adrenaline (as adrenaline tartrate).
- 1 ml of Septanest 1:100,000 contains 40 mg of articaine hydrochloride and 10 micrograms of adrenaline (as adrenaline tartrate).

- The other ingredients are sodium chloride, sodium metabisulfite (E223), sodium hydroxide and water for injections.

What Septanest looks like and contents 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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The following information is intended for healthcare professionals only:

Posology

For all populations, the lowest dose leading to effective anaesthesia should be used. The necessary dosage must be determined on an individual basis.

For a routine procedure, the normal dose for adult patients is of 1 cartridge, but the contents of less of a cartridge may be sufficient for effective anaesthesia. At the discretion of the dentist, more cartridges may be required for more extensive procedures without exceeding the maximum recommended dose.

Septanest 1:200,000 is indicated for use in most routine dental procedures.
For more complex procedures, such as requiring pronounced hemostasis, it is preferable to use Septanest 1:100,000.

Concomitant use of sedatives to reduce patient anxiety:
The maximum safe dose of local anaesthetic may be reduced in sedated patients due to an additive effect on central nervous system depression.

Adults and adolescents (12 to 18 years of age)
In adults and adolescents, the maximum articaine dose is 7 mg/kg with an absolute maximum articaine dose of 500 mg. The maximum articaine dose of 500 mg corresponds to a healthy adult of more than 70 kg body weight.

Children (4 to 11 years of age)
The safety of Septanest in children aged 4 years and below has not been established. No data are available.
The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation. The average effective dose is 2 mg/kg and 4 mg/kg for simple and complex procedures, respectively. The lowest dose providing effective dental anaesthesia should be used. In children aged 4 years (or from 20 kg (44 lbs) of body weight) and above, the maximum dose of articaine is 7 mg/kg only with an absolute maximum dose of 385 mg articaine for a healthy child of 55 kg body weight.

Special populations

Elderly and Patients with renal disorders:
Due to the lack of clinical data, particular precaution should be used in order to administer the lowest dose leading to effective anaesthesia in elderly patients and in patients with renal disorders.
Elevated product plasma levels may occur in these patients in particular after repeated use. In case of required reinjection, patient should be strictly monitored, to identity any sign of relative overdose.

Patients with hepatic impairment
Particular precaution should be used in order to administer the lowest dose leading to efficient anaesthesia in patients with hepatic impairment, in particular after repeated use, although 90% of articaine is first inactivated by unspecific plasma esterases in the tissue and blood.

Patients with plasma cholinesterase deficiency
Elevated product plasma levels may occur in patients with cholinesterase deficiency or under acetylcholinesterase inhibitors treatment since the product is inactivated at 90% by plasmatic esterases. Therefore, the lowest dose leading to effective anaesthesia should be used.

Method of Administration

Infiltration and perineural use in oral cavity.

Local anaesthetics should be injected with caution when there is inflammation and/or infection at the site of the injection. The rate of injection should be very slow (1 ml/min).

Precautions to be taken before handling or administering the medicinal product

This medicinal product should only be used by or under the supervision of physicians or dentists sufficiently trained and familiar with diagnosis and treatment of systemic toxicity. The availability of appropriate resuscitation equipment and medication should be ensured before induction of regional anaesthesia with local anaesthetics to enable prompt treatment of any respiratory and cardiovascular emergencies. The patient's state of consciousness should be monitored after each local anaesthetic injection.

When using Septanest for infiltration or regional block anaesthesia, injection should always be made slowly and with prior aspiration.

Special warnings

Adrenaline impairs the flow of blood in the gums, potentially causing local tissue necrosis.
Very rare cases of prolonged or irreversible nerve injury and gustatory loss have been reported after mandibular block analgesia.

Precautions for use

Risk associated with accidental intravascular injection:
Accidental intravascular injection may cause sudden high levels of adrenaline and articaine in the systemic circulation. This may be associated with severe adverse reactions, such as convulsions, followed by central nervous and cardiorespiratory depression and coma, progressing to respiratory and circulatory arrest.
Thus, to ensure that the needle does not penetrate a blood vessel during injection, aspiration should be performed before the local anaesthetic medicinal product is injected. However, the absence of blood in the syringe does not guarantee that intravascular injection has been avoided.

Risk associated with intraneural injection:
Accidental intraneural injection may lead the drug to move in retrograde manner along the nerve.
In order to avoid intraneural injection and to prevent nerve injuries in connection with nerve blockades, the needle should always be slightly withdrawn if electric shock sensation is felt by the patient during injection or if the injection is particularly painful. If needle nerve injuries occur, the neurotoxic effect could be aggravated by articaine potential chemical neurotoxicity and the presence of adrenaline as it may impair the perineural blood supply and prevent articaine local wash-out.

Treatment of overdose

The availability of resuscitation equipment and medication should be ensured before administration of regional anaesthesia with local anaesthetics to enable prompt treatment of any respiratory and cardiovascular emergencies.
The seriousness of overdose symptoms should have physicians/dentists to implement protocols that foresee the necessity of timely securing the airway and providing assisted ventilation.
The patient's state of consciousness should be monitored after each local anaesthetic injection.
If signs of acute systemic toxicity appear, injection of the local anaesthetic should be stopped immediately. Change patient position to supine position if necessary.
CNS symptoms (convulsions, CNS depression) must promptly be treated with appropriate airway/respiratory support and the administration of anticonvulsant drugs.

Optimal oxygenation and ventilation and circulatory support as well as treatment of acidosis may prevent cardiac arrest.
If cardiovascular depression occurs (hypotension, bradycardia), appropriate treatment with intravenous fluids, vasopressor, and/or inotropic agents should be considered. Children should be given doses commensurate with age and weight.
In case of cardiac arrest, immediate initiation of cardiopulmonary resuscitation should be performed.

Special precautions for disposal and other handling

This medicine should not be used if the solution is cloudy or discoloured.
To avoid risk of infection (e.g. hepatitis transmission), syringe and needles used to draw up the solution must always be fresh and sterile.
The cartridges are intended for single use. If only a portion of a cartridge is used, the remainder must be discarded.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.