Package Insert

SCHEDULING STATUS

SA: S4

NA: NS2

Botswana: S2

PROPRIETARY NAME AND DOSAGE FORM

Septanest with adrenaline 1/100 000 Solution for Injection

COMPOSITION

Per cartridge	1.7 ml	2.2 ml
Articaine hydrochloride	68.000 mg	88.000 mg
Epinephrine (adrenaline) tartrate expressed as base	30.94 mcg 17.00 mcg	40.04 mcg 22.00 mcg
Sodium metabisulphite (as antioxidant)	0.85 mg	1.1 mg

SEPTANEST WITH ADRENALINE 1/100 000 also contains water for injection as the inactive ingredient.

PHARMACOLOGICAL CLASSIFICATION

A. 4 – Local Anaesthetics

PHARMACOLOGICAL ACTION

Articaine is a local anaesthetic of the amide type.

The mechanism of action of articaine is by inhibition of the generation and the conduction of the action potential without change in resting potential.

Articaine blocks sodium channels and, with lower sensitivity, potassium channels at neutral pH.

When injected close to the sensitive nerve filaments, articaine has the reversible effect of blocking the conduction of painful sensations. The anaesthesia is obtained in about 3 minutes and lasts about 15 to 30 minutes with articaine alone.

Epinephrine (adrenaline) added to the solution reduces bleeding during surgery, slows down the passage of articaine into the general circulation and thus ensures the prolonged maintenance of an active tissue concentration.

SEPTANEST 1: 100 000, administered by infiltration of nerve block injection, provides anaesthesia in about 3 minutes. The pulpal analgesia lasts 75 minutes in adults.

Pharmacokinetic properties

Articaine is rapidly hydrolysed by plasmatic cholinesterases to its primary metabolite articainic acid. Which is further metabolized to articainic acid glucuronide. Articainic acid concentration peak is about 30 to 60 minutes after the peak in articaine concentration

Articaine is cleared from the body within 12 to 24 hours. Approximately 50 % of the dose is eliminated in the urine, 95 % as articainic acid and 2 % as articaine.

INDICATIONS

FOR USE IN DENTAL ANAESTHESIA ONLY.

SEPTANEST is indicated for local or loco-regional dental anaesthesia in patients of at least 4 years.

CONTRAINDICATIONS

- Hypersensitivity to SEPTANEST or any local anaesthetic agent,
- Hypersensitivity to any other component of SEPTANEST,
- Patients who have experienced bronchospasm after administration of any product which contains sulphites should not be given SEPTANEST,
- Patients who are known, or who have a history which suggests a deficiency in plasma cholinesterase activity (see section Pharmacokinetic properties),
- Patients receiving monoamine oxidase inhibitors (or who have received such an agent within two weeks) or tricyclic antidepressants,
- Patients in whom there is a possibility that general anaesthesia might be required to complete the procedure.
- Do not use in patients under 4 years of age.

WARNINGS and SPECIAL PRECAUTIONS

- Intra-vascular injection is strictly contraindicated. Accidental injection into a blood vessel may be associated with systemic adverse effects due to the circulating levels of epinephrine (adrenaline) and/or articaine. Therefore, it is imperative to ensure that the needle being used for the injection does not go into a vessel.

- Each time a local anaesthetic is used there should be available:
    - Anti-convulsant medicines (benzodiazepines or barbiturates which can be injected), myorelaxants, atropine and vasopressors and epinephrine (adrenaline) for a severe allergic or anaphylactic reaction.

- Resuscitating equipment (in particular a source of oxygen) enabling artificial ventilation if necessary.

SEPTANEST should not be used in patients with a deficiency of plasma cholinesterase activity.

- Since amide-type local anaesthetics are also metabolised by the liver, SEPTANEST should be used with caution in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolise local anaesthetics normally, are not at greater risk of developing toxic plasma concentration.
- Due to the presence of epinephrine (adrenaline), the product is not advised for diabetic subjects and for patients with thyrotoxicosis.
- The effects of local anaesthetics may be reduced if an injection is made into an inflamed or infected area.
- SEPTANEST should be administered with caution to subjects with cardiovascular disease, abnormalities of cardiac conduction, or a history of epilepsy.

Do not use in children under 4 years of age, ‘See Contraindications’.

One or more cartridges should be used on a single patient during each session of treatment.

If only a portion of a cartridge is used, the remainder must be discarded.

One or more cartridges should be used on a single patient during each session of treatment.

Any unused portion must be discarded

Effects on ability to drive and use machines

In a controlled study on healthy volunteers articaine was shown to have no effect on the level of attentiveness, reaction to visual stimulations or motor coordination.

Patients who experience systemic adverse effects during or immediately following administration of SEPTANEST should be advised to avoid driving or operating machinery until resolution of signs or symptoms.

INTERACTIONS

No drug interaction studies have been performed.

Due to the possibility that clinically significant increases in circulating epinephrine (adrenaline) concentrations may occur post-injection, SEPTANEST should be administered with caution to any patient receiving medicines with sympathomimetic properties or with agents whose therapeutic actions may be antagonised by epinephrine (adrenaline).

Articaine should be given with caution to any patients receiving an antiarrhythmic agent.

PREGNANCY AND LACTATION

- *Use in pregnancy:*

  Safe use of local anaesthetics during pregnancy has not been established.

- *Use during lactation*

  The excretion of articaine or its metabolites in human milk is unknown. Therefore, nursing mothers should breastfeed 48 hours following anaesthesia with SEPTANEST.

DOSAGE AND DIRECTIONS FOR USE

For most common operations, one infiltration with 1,7 ml SEPTANEST is sufficient in all cases, the injection must be done slowly (about 1 ml/min).

For an infiltration in the interdental septum, a quantity of 0,3 ml to 0,5 ml is indicated as generally sufficient.

Higher volumes should rarely be required.

Do not exceed the equivalent of 7 mg articaine hydrochloride per kilo of weight which corresponds, for a subject weighing 60 kg, to six (6) standard 1,7 ml cartridges or five (5) standard 2,2 ml cartridges (doses of 7 mg/kg were not exceeded in clinical trials). Anaesthesia is obtained rapidly (2 to 5 minutes).

Dosage in children should be commensurate with their weight:

<table>
<tr><td rowspan="3">Maximum dose:
0,175 ml/kg</td><td colspan="2">20 kg child</td><td colspan="2">40 kg child</td></tr>
<tr><td colspan="2">3,5 ml</td><td colspan="2">7,0 ml</td></tr>
<tr><td colspan="2">i.e. ≈ 2 cartridges of 1,7 ml
or
≈ 1,5 cartridge of 2,2ml</td><td colspan="2">i.e. ≈ 4 cartridges of 1,7 ml
or
≈ 3 cartridges of 2,2 ml</td></tr>
<tr><td>Recommended dose</td><td colspan="2">Procedure</td><td colspan="2">Procedure</td></tr>
<tr><td rowspan="3">0,06 ml/kg for simple procedure

0,07 ml/kg for</td><td>Simple</td><td>Complex</td><td>Simple</td><td>Complex</td></tr>
<tr><td>1,2 ml i.e. ≈ 3/4 cartridge of 1,7 ml</td><td>1,4 ml i.e. ≈ 3/4 cartridge of 1,7 ml</td><td>2,4 ml i.e. ≈1,5 cartridge of 1,7 ml</td><td>2,8 ml i.e. ≈1,5 cartridge of 1,7 ml</td></tr>
<tr><td>or</td><td>or</td><td>or</td><td>or</td></tr>
</table>

complex procedure	≈0.5 cartridge of 2,2 ml	≈0.5 cartridge of 2,2 ml	≈1 cartridge of 2,2 ml	≈1 cartridge of 2,2 ml

The duration of anaesthesia during which an operation can be performed is about one hour (pulpal analgesia) depending on the technique used, and on the procedure.

Do not exceed the recommended dose.

SIDE EFFECTS

Articaine and epinephrine (adrenaline) may reach sufficient concentrations in the blood to provoke systemic adverse effects.

Reactions due to articaine:

The following side effects have been reported and the frequencies are unknown.

Toxic reactions (showing an abnormally high concentration of local anaesthetic in the blood) may appear either immediately, by accidental intra-vascular injection, or later by true overdose following an injection of an excessive quantity of anaesthetic solution, one may observe:

Nervous system Disorder:

Nervousness, shaking, yawning, trembling, apprehension, nystagmus, logorrhoea, headache, nausea, buzzing in the ears. These signs, when they appear, require rapid corrective measures to prevent possible worsening.

Respiratory disorders:

Tachypnoea, then bradycardia, which could lead to apnoea.

Cardiovascular Disorders:

Reduction in the contractile power of the myocardium, lowering of heart rate and drop in blood pressure.

Other adverse reactions due to Articaine:

Nervous system disorders

Incidence greater than 1%:

- Headache, face oedema, gingivitis,
- Disruption of nerve transmission (para-, hypo- and dysaesthesia) may appear after articaine administration.

  Resolution usually occurs within eight weeks.

Gastrointestinal disorders:

Incidence less than 1%:

Nausea

General disorders and administration site conditions

Very rare:

One may observe manifestations of hypersensitivity to articaine as rash, pruritis, urticaria or anaphylaxis.

The administration of large doses of articaine may produce methaemoglobinaemia in patients with subclinical methaemoglobinaemia.

Allergic reactions due to sulphites:

The following side effects have been reported and the frequencies are unknown:

Immune system disorders:

Allergic-type reactions may occur in patients with bronchial asthma due to hypersensitivity to the sulphite component and may be manifested by dermatologic reactions, oedema, urticaria and other allergy symptoms.

Adverse events due to Epinephrine (adrenaline):

The following side effects have been reported and the frequencies are unknown:

Vascular disorders:

Patients with peripheral vascular disease and those with hypertensive vascular disease may exhibit exaggerated vasoconstrictor response, Ischaemic injury or necrosis may results.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

The most serious effects of articaine intoxication are on the CNS and cardiovascular system. The type of toxic reaction is unpredictable and depends on such factors as dosage, rate of absorption, and clinical status of the patient. Two types of reactions that effect stimulation and/or depression of the central cortex and medulla may result from the systemic absorption.

Slow onset symptoms following overdose include stimulation leading to nervousness, dizziness, blurred vision, nausea, tremors, convulsions, hypotension, cardiovascular depression, and respiratory arrest.

Rapid onset symptoms following overdose include depression, leading primarily to respiratory arrest, cardiovascular collapse, and cardiac arrest. Since cardiac arrest symptoms may occur rapidly and with little warning, treatment should be readily available.

Supportive treatment should be given; specific therapy may be required to counter adverse effects on the cardiovascular and/or respiratory systems and to control convulsions. There is no specific antidote.

IDENTIFICATION

A clear and colourless solution, free from visible particles in a 2 ml and 4 ml clear glass vial cartridge with a rubber closure.

PRESENTATION

Unit cartons containing 5 transparent PVC blister trays of 10 X 1,7 ml or 10 X 2,2 ml cartridges.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Store in original container protected from light. Do not freeze

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

SA: A38/4/0412

NA: 1,7 ml: 12/4/0202

NA: 2,2 ml: 12/4/0203

Botswana: BOT1803307

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Henry Schein Dental Warehouse (Pty) Ltd

106 16th Road

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RSA

DATE OF PUBLICATION OF THE PACKAGE INSERT

26 May 2006

Date of the most recently revised package insert as approved by council:

20 October 2021