PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NA: NS2

Botswana: S2

SEPTANEST WITH ADRENALINE 1:100 000

Solution for Injection

Per cartridge	1.7 ml	2.2 ml
Articaine hydrochloride	68.000 mg	88.000 mg
Epinephrine (adrenaline) tartrate	30.94 mcg	40.04 mcg
expressed as base	17.00 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.

Read all of this leaflet carefully before you are given SEPTANEST WITH ADRENALINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- SEPTANEST WITH ADRENALINE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What SEPTANEST WITH ADRENALINE is and what it is used forSEPTANEST WITH ADRENALINE is used to numb (anaesthetise) your oral cavity before and during dental procedures.

It contains two active ingredient: articaine hydrochloride, a local anaesthetic which prevents pain and adrenaline tartrate, a vasoconstrictor which narrows the blood vessels at the site of injection, and thereby makes the effect last longer and it also decreases the bleeding during dental surgery.

2. What you need to know before you use SEPTANEST WITH ADRENALINE

Do not use SEPTANEST WITH ADRENALINE

- If you are hypersensitive (allergic) to articaine or adrenaline (epinephrine) or any of the other ingredients of SEPTANEST WITH ADRENALINE (listed in section 6).
- If you are allergic to any other local anaesthetics of the same class.
- If you suffer from allergy or asthma, SEPTANEST WITH ADRENALINE contains sodium metabisulphite. Sodium metabisulphite can cause allergic-type reactions including anaphylactic symptoms and bronchospasm (difficulty

in breathing) in some people. This is more likely to happen if you suffer from allergy or asthma.

- In patients who are known, or who have a history which suggests a deficiency in plasma cholinesterase activity.
- In patients receiving monoamine oxidase inhibitors (or who have received such an agent within two weeks) or tricyclic antidepressants.
- In patients under 4 years of age.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- If you have liver problems.
- If you have diabetes or an overactive thyroid gland, whether or not you are being treated for this.
- If you have an inflamed or infected injection area.
- If you have a problem with your heart, your blood vessels, or your heart rhythm.
- If you are epileptic or have a history of epilepsy.
- If you have asthma (or used to), because SEPTANEST WITH ADRENALINE can bring on an attack.
- If you are pregnant or breastfeeding.

Other medicines and SEPTANEST WITH ADRENALINE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your dentist if you are taking any of the following medicines:

- Medicines with sympathomimetic properties or with agents whose therapeutic actions may be antagonised by epinephrine (adrenaline).
- Antiarrhythmic medicines, articaine should be given with caution to any patients receiving these.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent SEPTANEST WITH ADRENALINE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which SEPTANEST WITH ADRENALINE affects them.

3. How to use SEPTANEST WITH ADRENALINE

Do not share medicines prescribed for you with any other person.

SEPTANEST WITH ADRENALINE will usually be given to you by a doctor or dentist. The dose that your doctor or dentist gives you will depend on the type of pain relief that you need. It will also depend on your age and physical condition.

Any unused portion of the medicine will be discarded by your dentist.

If you use more SEPTANEST WITH ADRENALINE than you should

Since a health care provider will administer SEPTANEST WITH ADRENALINE, he/ she will control the dosage. However, in the event of overdosage your doctor or dentist will manage the overdosage.

If you forget to use SEPTANEST WITH ADRENALINE

Since a health care provider will administer SEPTANEST WITH ADRENALINE, it is unlikely that the dose will be missed.

Possible side effects

SEPTANEST WITH ADRENALINE can have side effects.

Not all side effects reported for SEPTANEST WITH ADRENALINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SEPTANEST WITH ADRENALINE, please consult your health care provider for advice.

If any of the following happens, stop taking / using SEPTANEST WITH ADRENALINE and tell your doctor or dentist immediately or go to the casualty department at your nearest hospital:

- Swelling of your face, lips, tongue, or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet, and ankles.
- Difficulty breathing.
- Severe itching of the skin (with raised lumps).

These are all very serious side effects. If you have them, you may have had a serious reaction to SEPTANEST WITH ADRENALINE. You may need urgent medical attention or hospitalisation.

Tell your doctor or dentist if you notice any of the following:

Less frequent

- Toxic reactions (showing an abnormally high concentration of local anaesthetic in the blood)
- Nervousness
- Shaking

- Yawning
- Trembling
- Apprehension
- Rapid involuntary movements of the eyes
- Excessive and often incoherent talkativeness or wordiness
- Headache
- Nausea
- Buzzing in the ear
- Breathing that is abnormally rapid and often shallow
- Abnormal slow heart rate, which could lead to breathing stoppage
- Reduction in the contractile power of the heart muscle, lowering of heart rate and drop in blood pressure
- Swollen face
- Inflamed gums
- Disruption of nerve transmission
- Rash
- Severe itching of the skin
- Hives
- A severe, potentially life-threatening allergic reaction
- Blood disorder in which an abnormal amount of the protein in the red blood cells is produced
- Bronchial asthma due to hypersensitivity to the sulphite component
- Exaggerated vasoconstrictor response, reduced blood flow or necrosis (death of cells or tissue) may result due to adrenaline in patients with peripheral vascular disease and those with hypertensive vascular disease

If you notice any side effects not mentioned in this leaflet, please inform your doctor, dentist, or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SEPTANEST WITH ADRENALINE.

4. How to store SEPTANEST WITH ADRENALINE

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original container and protected from light.

Do not freeze.

Do not use after the expiry date stated on the label / carton / bottle

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

5. Contents of the pack and other information

What SEPTANEST WITH ADRENALINE contains

- The two active substances are articaine hydrochloride, a local anaesthetic and adrenaline tartrate.
- The other ingredients are sodium chloride, sodium metabisulphite and sodium hydroxide.

What SEPTANEST WITH ADRENALINE looks like and contents of the pack

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

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

Holder of Certificate of Registration

Henry Schein Dental Warehouse (Pty) Ltd

106 16th Road

Building 2

Midrand

1686

RSA

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