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רח' קלישר 27, ת"א 65165

מרץ 2021

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

<u>הנדון: עדכון העלון לרופא של התכשירים</u>
<u>SEPTANEST N and SEPTANEST SP – SP ספטאנסט N ו- ספטאנסט</u>
Articaine Hydrochloride 40 mg/ml and Adrenaline 5 mcg/ml Solution for injection
Articaine Hydrochloride 40 mg/ml and Adrenaline 10 mcg/ml Solution for injection

חברת א. לוי דנטל דפו בע"מ מבקשת להודיע על <u>עדכון העלון לרופא</u> של התכשירים ספטאנסט N ו- ספטאנסט SP – Septanest N and Sesptanest SP.

בהודעה זו מצויינים העדכונים המהותיים בלבד בעלון לרופא. בעלון ישנם שינויים נוספים.

התוויה הרשומה לתכשיר בישראל (נותרה <u>ללא שינוי</u>):

SEPTANEST N and SEPTANEST SP are indicated for infiltration anaesthesia and nerve block anaesthesia in clinical dentistry. This includes local or loco-regional dental anaesthesia suitable for operations such as: single extractions, with no complications; multiple extractions ; extractions of impacted teeth; trephinement; apical resections; removal of cysts; alveolectomies ; preparation of cavity; biopulpectomies; and maxillo-facial surgery. SEPTANEST N and SEPTANEST SP are also suitable for muco-gingival operations and other surgical operations on the bone when long lasting ischaemia and analgesia are required.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

2) Qualitative and quantitative composition:
<u>SEPTANEST N:</u>
1 ml of solution for injection contains 40 mg of articaine hydrochloride and 5 micrograms of adrenaline (as adrenaline tartrate).
Each cartridge of 1.7 ml of solution for injection contains 68 mg of articaine hydrochloride and 8.5 micrograms of adrenaline (as adrenaline tartrate).

<u>SEPTANEST SP:</u>
1 ml of solution for injection contains 40 mg of articaine hydrochloride and 10 micrograms of adrenaline (as adrenaline tartrate).
Each cartridge of 1.7 ml of solution for injection contains 68 mg of articaine hydrochloride and 17 micrograms of adrenaline (as adrenaline tartrate).

<u>Excipient(s) with known effect</u>: sodium metabisulfite (E223), sodium chloride, disodium edetate, sodium hydroxide.
SEPTANEST N and SEPTANEST SP contain 0.804 mg sodium per 1 ml of solution i.e. 1.44 mg/1.7 ml.
For the full list of excipients, see section 6.1.

4.4 Special warnings and precautions for use:
Before using this medicinal product, it is important:
- To make inquiries into the patient's current therapies and history;
- To maintain verbal contact with the patient
- To have resuscitative equipment at hand (see section 4.9)

Special warnings: This medicinal product must be used with special caution in patients with the following disorders and postponement of dental surgery should be considered if the condition is severe and/or unstable.

Patients with cardiovascular disorders: The lowest dose leading to efficient anaesthesia should be used in case of:
- Cardiac impulse formation and conduction disturbances (e.g. 2nd or 3rd degree atrioventricular block, marked bradycardia)
- Acute decompensated heart failure (acute congestive heart failure)
- Hypotension
- Patients with paroxysmal tachycardia or absolute arrhythmias with rapid heart rate
- Patients with unstable angina or a history of recent (less than 6 months) myocardial infarction
- Patients with recent (3 months) coronary artery bypass surgery
- Patients taking non-cardioselective beta-blockers (e.g. propranolol) (risk of hypertensive crisis or severe bradycardia), (see section 4.5)
- Patients with uncontrolled hypertension
- Concomitant treatment with tricyclic antidepressants, as these active substances can intensify the cardiovascular effects of adrenaline. (see section 4.5)

This medicinal product must be used with caution in patients with the following disorders:

Patients with epileptic disease: Because of their convulsive actions, all local anaesthetics should be used very cautiously.

Patients with plasma cholinesterase deficiency: A plasma cholinesterase deficiency can be suspected when clinical signs of overdose occurs with usual dosage of anesthesia and when a vascular injection has been excluded. In this case, caution shall be used for the next injection and reduced dose shall be applied.

Patients with renal disease: The lowest dose leading to effective anaesthesia should be used.

Patients with severe hepatic disease: This medicinal product should be used cautiously due to the presence of hepatic disease although 90% of articaine is first inactivated by unspecific plasma esterases in the tissue and blood.

Patients with myasthenia gravis treated by acetylcholinesterase inhibitors: The lowest dose leading to effective anaesthesia should be used.

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Patients with porphyria: SEPTANEST N and SEPTANEST SP should only be used in patients with acute porphyria when no safer alternative is available. Appropriate precautions should be taken in all patients with porphyria, as this medicinal product can trigger porphyria.

Patients with concomitant treatment with halogenated inhalation anaesthetics: The lowest dose of the medicinal product leading to effective anaesthesia should be used (see section 4.5).

Patients receiving treatment with antiplatelets / anticoagulants: SEPTANEST N and SEPTANEST SP should be administered with caution in patients, who are using antiplatelet/anticoagulant medicines or are suffering from coagulation disorder, because of higher risk of bleeding. The higher risk of bleeding is more associated with the procedure, rather than with the medicine.

Elderly patients: Elevated product plasma levels may occur in elderly patients in particular after repeated use. In case of required reinjection, patient should be strictly monitored, to identity any sign of relative overdose (see section 4.9).
Therefore, the lowest dose leading to effective anaesthesia should be used.

The use of SEPTANEST N over SEPTANEST SP should be considered on account of its lower adrenaline content of 5 micrograms/ml in:

- *Patients with cardiovascular diseases* (e.g. heart failure, coronary heart disease, history of myocardial infarction, cardiac arrhythmia, hypertension)
- *Patients with cerebral circulation disturbances, history of strokes:* It is recommended that dental treatment with articaine/adrenaline be deferred for six months following a stroke due to the increased risk of recurrent strokes.
- *Patients with uncontrolled diabetes:* This medicinal product should be used cautiously due to hyperglycemic effect of adrenaline.
- *Patients with thyreotoxicosis:* This medicinal product should be used cautiously due to the presence of adrenaline.
- *Patients with pheochromocytoma:* This medicinal product should be used cautiously due to the presence of adrenaline.
- *Patients with susceptibility of acute angle-closure glaucoma:* This medicinal product should be used cautiously due to the presence of adrenaline.

The lowest dose leading to effective anaesthesia should be used.

This medicinal product must be used safely and effectively under appropriate conditions:
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.

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The local anaesthetic effects may be reduced when this medicinal product is injected into an inflamed or infected area.

The dose must also be reduced in case of hypoxia, hyperkalaemia and metabolic acidosis.

Risk of biting trauma (lips, cheeks, mucosa, and tongue) exists, especially in children; the patient should be told to avoid chewing gum or eating until normal sensation is restored.

This medicinal product contains sodium metabisulfite, a sulfite that may rarely cause hypersensitivity reactions and bronchospasm.

This medicinal product contains less than 1 mmol sodium (23 mg) per cartridge, i.e. it is considered as essentially “sodium free”.

If there is any risk of an allergic reaction, choose a different medicine for anesthesia (see section 4.3).

קיימים עדכונים נוספים. למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום א. לוי דנטל דפו בע"מ, רחוב קלישר 27, תל אביב 6516506. טלפון: 03-5173150. דואר אלק':
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בברכה,
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