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א. לוי
דנטל דפו בע"מ
יבואני אספקה וציוד דנטליים,
מוצרים לבתי מרקחות
רח' קלישר 27, ת"א 65165

דצמבר 2020

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

<u>הנדון: עדכון העלון לרופא של התכשיר</u>
<u>XYLONOR EPINEPHRINE – קסילונור אפינפרין</u>
Lidocaine Hydrochloride (as Monohydrate) 2% and
Adrenaline (as Tartrate) 1:80,000 Solution for injection

חברת א. לוי דנטל דפו בע"מ מבקשת להודיע על <u>עדכון העלון לרופא</u> של התכשיר קסילונור אפינפרין – Xylonor Epinephrine.

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

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

For the production of local anaesthesia for dental procedures by infiltration or nerve block injections.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

2) Qualitative and quantitative composition:
1 ml of solution for injection contains 20 mg of Lidocaine Hydrochloride (as Monohydrate) and 12.5 micrograms (1:80,000) of Epinephrine (as Bitartrate).

Epinephrine Bitartrate and also called Adrenaline Tartrate. Both names are synonyms.

One cartridge of 1.7 ml of solution for injection contains 34 mg of Lidocaine Hydrochloride (as Monohydrate) and 21.25 micrograms of Epinephrine (as Bitartrate).

<u>Excipient(s) with known effect:</u> This medicinal product contains 1.20 mg/ml Potassium Metabisulfite (E224) [equivalent to 0.422 mg/ml Potassium (0.0108 mmol/ml)], and 2.602 mg/ml Sodium [0.11 mmol/ml].

For a 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 diathesis, current therapies and history;
- To maintain verbal contact with the patient;
- To have resuscitative equipment at hand (see section 4.9).

<u>Special warnings:</u> ***This product must be used with caution in***:
<u>Patients with cardiovascular disorders:</u>
- Peripheral vascular disease.
- Arrhythmias particularly of ventricular origin;
- Heart failure;
- Hypotension.

The product should be administered with caution in patients with impaired cardiac function since they may be less able to compensate changes due to the prolongation of atrio-ventricular conduction.

Patients with *myasthenia gravis*: The lowest dose leading to effective anaesthesia should be used as these patients are particularly sensible to the effect of local anaesthetics.

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

Patients with hepatic disease: The lowest dose leading to efficient anaesthesia should be use, see section 4.2.

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

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

Patients with coronary artery disease and valvular cardiac disease: The lowest dose leading to effective anaesthesia should be used.

Patients receiving treatment with antiplatelets / anticoagulants: The increased risk of severe bleeding after accidental vessel puncture and during oro-maxillo-facial surgery should be considered. INR monitoring should be increased in patients under anticoagulants.

Patients with uncontrolled diabetes: This product should be used cautiously due to hyperglycemic effect of epinephrine (adrenaline).

Patients with susceptibility of acute angle-closure glaucoma: This product should be used cautiously due to the presence of epinephrine (adrenaline).

Patients under the influence of illicit drug: The efficacy of this product may be decreased in these patients.

Elderly patients: Dosages should be reduced in elderly patients over 70 years old (lack of clinical data).

The product must be used safely and effectively under appropriate conditions: Epinephrine (Adrenaline) impairs the flow of blood in the gums, potentially causing local tissue necrosis. The local anaesthetic effects may be reduced if the product is injected into an inflamed or infected area.
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 sensation is restored.

Precautions for use:
Risk associated with an accidental intravascular injection: Accidental intravascular injection (e.g.: inadvertent intravenous injection into the systemic circulation, inadvertent intravenous or intra-arterial injection in the head area and neck area) may be associated with severe adverse reactions, e.g., convulsions, followed by central nervous system or cardiorespiratory depression and coma, progressing ultimately to respiratory arrest, due to the sudden high level of adrenaline and / or lidocaine in the systemic circulation.

Risk associated with intraneural injection: Accidental intraneural injection may lead the drug to move in retrograde manner along the nerve.

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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 lidocaine's potential chemical neurotoxicity and the presence of adrenaline as it may impair the perineural blood supply and prevent lidocaine local wash-out.

Risk of Takotsubo cardiomyopathy or stress-induced cardiomyopathy: Stress cardiomyopathy induced by injected catecholamines has been reported.
Because of the presence of adrenaline, precautions and monitoring should be enhanced in the following situations: patients stressed prior to dental procedure or conditions of use which may contribute to induce a systemic passage of adrenaline e.g. an administered dose higher than recommended or in case of an accidental intravascular injection.
Any previous knowledge of such underlying conditions in patients requiring dental anaesthesia should be minded and a minimal dose of local anaesthetic with vasoconstrictor used.
The medicinal product contains potassium metabisulfite, a sulfite that may rarely cause hypersensitivity reactions and bronchospasm.
The medicinal product contains potassium, less than 1 mmol (39 mg) for a maximal dose of 16 ml, i.e. essentially 'potassium-free'.
The medicinal product contains 0.1132 mmol/ml (2.602 mg/ml) sodium (main component of cooking/table salt). This is equivalent to approximately 0.665% of the recommended maximum daily dietary intake of sodium for an adult.
The maximum recommended dose of this medicinal product (3 cartridges equivalent to 5.1 ml) contains 0.5773 mmol (13.27 mg) sodium, which is equivalent to 3.39% of the recommended maximum daily intake of sodium for an adult.
Concomitant use of the other medicinal products may require thorough monitoring (See section 4.5).

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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