



מרץ 2021

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון: עדכון העלון לרופא של התכשיר
סקנדונסט 3% ללא מצר כלי דם – SCANDONEST 3% WITHOUT
VASOCONSTRICTOR
Mepivacaine Hydrochloride 3% Solution for injection

חברת א. לוי דנטל דפו בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר סקנדונסט 3% ללא מצר כלי דם – Scandonest 3% Without Vasoconstrictor –

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

התוויה הרשומה לתכשיר בישראל (נותרה ללא שינוי):

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

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

2) Qualitative and quantitative composition:

1 ml solution for injection contains 30 mg of mepivacaine hydrochloride.

Each cartridge of 1.7 ml of solution for injection contains 51 mg of mepivacaine hydrochloride.

Excipient(s) with known effect: each ml contains 0.11 mmol of sodium (2.467 mg/ml).

For the full list of excipients, see section 6.1.

4.4 Special warnings and precautions for use:

Special warnings: If there is any risk of an allergic reaction, choose different medicine for anaesthesia (see Section 4.3).

Mepivacaine must be used safely and effectively under appropriate conditions:

The local anaesthetic effects may be reduced when SCANDONEST 3% WITHOUT VASOCONSTRICTOR 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 normal sensation is restored.

Mepivacaine must be used with caution in:

Patients with cardiovascular disorders:

- Peripheral vascular disease,
- Arrhythmias particularly of ventricular origin,
- Atrio-ventricular conduction disorders,
- Heart failure,
- Hypotension.



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

Epileptic patients: Because of their convulsive actions, all local anaesthetics should be used very cautiously. For poorly controlled epileptic patients, see section 4.3.

Patients with a hepatic disease: The lowest dose leading to efficient anaesthesia should be used.

Patients with a kidney disease: The lowest dose leading to efficient anaesthesia should be used.

Patients with porphyria: SCANDONEST 3% WITHOUT VASOCONSTRICTOR should only be used to patients with acute porphyria when no safer alternative is available. Caution should be taken in all patients with porphyria, as this medicinal product may trigger porphyria.

Patients with acidosis: Caution should be used in case of acidosis such as worsened of renal insufficiency or poorly control of type 1 diabetes mellitus.

Elderly patients: Dosages should be reduced in elderly patients (due to lack of clinical data). Mepivacaine should be administered with caution in patients, who are using antiplatelet / anticoagulant medicines or are suffering from a coagulation disorder, because of higher risk of bleeding. The higher risk of bleeding is more associated with the procedure, rather than with the medicine.

Precautions for use: Local anaesthetics should only be employed by healthcare professionals who are well versed in diagnosis and management of dose-related toxicity and other acute emergencies which might arise from the block to be employed. The immediate availability of oxygen, other resuscitative drugs, cardiopulmonary resuscitative equipment, and the personnel resources needed for proper management of toxic reactions and related emergencies should be considered (see section 4.2). Delay in proper management of dose-related toxicity, under ventilation from any cause, and/or altered sensitivity may lead to the development of acidosis, cardiac arrest and, possibly, death.

Hypoxaemia and metabolic acidosis may potentiate the cardiovascular toxicity. Early control of seizures and aggressive airway management to treat hypoxaemia and acidosis may prevent cardiac arrest.

Concomitant use of the other medicinal products may require thorough monitoring (see section 4.5).

This medicinal product contains 24.67 mg sodium per 10 ml (maximum recommended dose), equivalent to 1.23 % of the WHO recommended maximum daily intake of 2g sodium for an adult.

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

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