

July 2024

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,**MEPIVACAINE HCl 3% INJECTION**

חברת הנרי שיין שוודנט מבקשת להודיע על עדכון בהתוויה ובמשטר המינון של התכשיר וכן על עדכונים בעלון לרופא של התכשיר.

התווית התכשיר המעודכנת:

For local and loco-regional anaesthesia in dental surgery in adults, adolescents and children above 4 years of age (calculated as 20 kg of body weight).

מרכיב פעיל:

Mepivacaine hydrochloride

DENTAL INFILTRATION INJ. , DENTAL NERVE BLOCK

צורת המתן של התכשיר :**עדכונים בעלון לרופא של התכשיר****4.1 Posology and method of administration:**

The medicinal product should only be used by or under the supervision of dentists, stomatologists or other clinicians sufficiently trained and familiar with diagnosis and treatment of systemic toxicity. The availability of appropriate resuscitation equipment and medication and adequately trained staff is recommended before induction of regional anaesthesia with local anaesthetics to enable prompt treatment of any respiratory and cardiovascular emergencies. The patient's state of consciousness should be monitored after each local anaesthetic injection.

Posology: As the absence of pain is related to the patient individual sensibility, the lowest dose of anaesthetic leading to effective anaesthesia should be used. For more extensive procedures one or more cartridges may be required, without exceeding the maximum recommended dose. For adults, the maximum recommended dose is of 4.4 mg/kg of body weight with an absolute maximum recommended dose of 300 mg for the individuals above 70 kg of body weight corresponding to 10 ml of solution. Of note, the maximum quantity has to take into account the patient's body weight. As patients possess different body weights, each patient possess a different maximum allowed quantity of mepivacaine that can tolerate. Additionally, there are important individual variations with regards to the onset and duration of action.

The following table lists the maximum allowed doses in adults for the most commonly used anaesthetic techniques and the equivalent in number of cartridges:

Weight (kg)	Mepivacaine hydrochloride dose (mg)	Volume (ml)	Equivalent* in cartridge numbers (1.7 ml)
50	220	7.3	4.0
60	264	8.8	5.0
≥70	300	10.0	5.5

* Rounded to the nearest half-cartridge

Paediatric population: MEPIVACAINE HCl 3% INJECTION is contraindicated in children below 4 years of age (calculated as 20 kg body weight) (see section 4.3).

Recommended therapeutic dose: The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation. The average dosage is 0.75 mg/kg = 0.025 ml of mepivacaine solution per kg body weight: ~ ¼ cartridge (15 mg of mepivacaine hydrochloride) for a 20 kg child.

Maximum recommended dosage: The maximum recommended dose in pediatric population is 3 mg of mepivacaine/kg (0.1 ml mepivacaine/kg).

The following table lists the maximum allowed dose in children and the equivalent in number of cartridges:

Weight (kg)	Mepivacaine hydrochloride dose (mg)	Volume (ml)	Equivalent* in cartridge numbers (1.7 ml)
20	60	2	1.2
35	105	3.5	2.0
45	135	4.5	2.5

* Rounded to the nearest half-cartridge

[...]

Method of administration: Infiltration and perineural use. For single use.

Precautions to be taken before administering the medicinal product: The medicinal product should not be used if cloudy and discoloured. The rate of injection should not exceed 1 ml of solution per minute. Local anaesthetics should be injected with caution when there is inflammation and/or infection at the site of the injection. The injection rate shall be very slow (1 ml/min).

4.3 Contraindications:

[...]

- Children below 4 years of age (ca.20 kg body weight).

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: <https://israel drugs.health.gov.il/#!/byDrug> ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת הנרי שיין שוודנט

בברכה,

מירי חזן
רוקחת ממונה