3M ESPE

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Mepivastesin™

Solution for injection

Active substance:
Mepivacaine hydrochloride

Oromucosal use
For use in dental anesthesia only

INFORMATION FOR USE

Registration No 129 70 24746 00

Name and address of importer and registration holder
3M Israel
91 Medinat Hayehudim St., Herzlia 46120

Name and address of manufacturer
3M Deutschland GmbH
Carl-Schurz-Straße 1
41453 Neuss
Germany

44000721959/04

COMPOSITION

1 ml solution for injection contains:

Active ingredient:
Mepivacaine hydrochloride 30 mg

Other ingredients:
Sodium chloride
Water for injections
Sodium hydroxide solution 9 % for adjusting the pH value

PHARMACEUTICAL FORM AND CONTENT

Solution for injection; 50 cartridges of 1.7 ml each

Local anesthetic of the amide type for administration in dentistry

THERAPEUTIC INDICATIONS

Infiltration anesthesia and nerve-block in dentistry.

MEPIVASTESIN is indicated for simple extractions as well as cavity and stump preparations.

MEPIVASTESIN is especially suitable for patients to whom vasoconstricting additives are contra-indicated.

CONTRAINDICATIONS

Due to the local anesthetic ingredient mepivacaine, MEPIVASTESIN is not allowed to be used in the event of

- known allergy or hypersensitivity to local anesthetics of the amide type
- severe impairment of the nervous impulses and conduction system of the heart (e.g. grade II and III AV block, pronounced bradycardia (slow heart rate))
- acutely decompensated cardiac insufficiency (acute failure of cardiac output)
- severe hypotension (very low blood pressure)

MEPIVASTESIN must be used with particular caution in the event of

- severe impairment to the renal or hepatic function
- angina pectoris (tightness in the chest)
- arteriosclerosis (vascular sclerosis)
- injection into an inflamed (infected) area
- considerable impaired blood coagulation

MEPIVASTESIN must be used with particular caution in the event of:

Pregnancy

There are no clinical studies regarding the application of mepivacaine hydrochloride during pregnancy. Animal studies have not provided adequate insights in view of possible effects of mepivacaine hydrochloride on pregnancy, embryofetal development, childbirth and postnatal development.

Mepivacaine hydrochloride passes the placental barrier and reaches the unborn child.

As compared to other local anesthetics, when using mepivacaine during the first trimester of the pregnancy an increased risk of malformations cannot be excluded, during early pregnancy mepivacaine should only be used, if no other local anesthetics are available.

Lactation

It is unknown in which doses mepivacaine hydrochloride reaches the breast milk. If its application is necessary during lactation, breastfeeding may be resumed after about 24 hours.

PRECAUTIONS FOR USE

Please note that with patients taking anticoagulants (e.g. heparin or acetyl salicylic acid), an inadvertent vascular puncture during injection may lead to severe hemorrhage, and the hemorrhage disposition is generally increased (see section "Drug Interactions").

Erroneous intravascular application must be avoided (see section: Posology and method of administration).

Effects on the ability to drive and use machinery

In sensitive patients, the injection of MEPIVASTESIN may be followed by a temporary impairment of reactions, e.g. in traffic. The physician must

decide from case to case whether the patient should be allowed to operate a motor vehicle or machinery.

Cardiovascular reactions are depressant. They may be the result of direct drug effect, the result of vasovagal reaction, particularly if the patient is in the sitting position. Failure to recognize premonitory signs such as sweating, feeling of faintness, changes in pulse or sensorium may result in progressive cerebral hypoxia and seizure, or serious cardiovascular catastrophe.

Place patient in recumbent position and administer oxygen. Vasoactive drugs such as ephedrine or methoxamine may be administered i.v.

Elderly: Repeated doses may cause accumulation of the drug or its metabolites or slow metabolic degradation. Give reduced doses.

DRUG INTERACTIONS

Which other pharmaceuticals influence the effect of MEPIVASTESIN?

- During treatment with anticoagulants, the hemorrhage disposition is generally increased (see section "Precautions for Use").
- Patients treated with antiarrhythmics may experience a summation of side effects after the application of Mepivastesin.
- Toxic synergism is described for central analgesics, sedatives, chloroform, eter and thiopental.

SPECIAL WARNINGS

Not applicable

POSOLOGY AND METHOD OF ADMINISTRATION

The following dosage instructions apply:

The smallest possible volume of solution which will lead to effective anesthesia should be used.

As a rule, doses of 1–4 ml are sufficient.

In children weighing about 20–30 kg, doses of 0.25–1 ml are sufficient; and in children weighing 30–45 kg, 0.5–2 ml.

Increased plasma levels of MEPIVASTESIN can occur in older patients due to diminished metabolic processes and lower distribution volume. The risk of accumulation of MEPIVASTESIN increases in particular due to repeated application (e.g. post-injection). A similar effect can ensue from the reduced general condition of the patient, as well as severely impaired hepatic and renal function. A lower dosage range is thus recommended in all such cases (minimum quantity for sufficient anesthetic depth).

The MEPIVASTESIN dose is to be likewise reduced in patients with certain pre-existing diseases (angina pectoris, arteriosclerosis).

Maximum Recommended Dosage:

Adults:

For healthy adults, the maximum dose is 4 mg/kg body weight (BW) mepivacaine equivalent to 0.133 ml Mepivastesin/kg BW. This means 300 mg mepivacaine or 10 ml Mepivastesin for patient with 70 kg BW.

Children:

The quantity to be injected should be determined by the age and weight of the child and the magnitude of the operation. Do not exceed the equivalent of 4 mg mepivaine/kg (0.133 ml Mepivaistesin/kg) of body weight.

Method of administration

Oromucosal use
For use in dental anesthesia only

To avoid intravascular injection, aspiration control in two planes (rotation of the needle by 180°) must always be carefully undertaken, although a negative aspiration result does not safely rule out an unintentional and unnoticed intravascular injection.

The injection rate should not exceed 0.5 ml in 15 seconds, i.e. 1 cartridge per minute.

Major systemic reactions as a result of accidental intravascular injection can be avoided in most cases by an injection technique – after aspiration slow injection of 0.1–0.2 ml and slow application of the rest – not earlier than 20–30 seconds later.

Opened cartridges must not be used in other patients.
Residues must be discarded.

THERAPY OF OVERDOSE

Undesirable effects (showing an abnormally high local anesthetic concentration in the blood) may either occur immediately (caused by inadvertent intravascular injection or abnormal absorption conditions, e.g. in inflamed or highly vascularized tissue) or later (caused by true overdose due to injection of an excessive volume of the anesthetic solution), and manifest themselves as central nervous and/or vascular symptoms.

Therapy

If side effects occur, the application of the local anesthetic is to be interrupted.

General basic measures:

Diagnostics (respiration, circulation, consciousness), maintenance/ restoration of the vital functions of respiration and circulation, oxygen administration, intravenous access.

Special measures:

Hypertension:	Elevation of the upper body, if necessary sublingual nifedipine
Convulsions:	Protect patients from concomitant injuries, if necessary diazepam i.v.
Hypotension:	Horizontal position, if necessary intravascular infusion of an electrolyte solution, vasopressors (e.g. etilefrine i.v.)
Bradycardia:	Atropine i.v.
Anaphylactic shock:	Contact emergency physician, in the meantime shock positioning, generous infusion of an electrolyte solution, if necessary epinephrine i.v., cortisone i.v.
Cardiac shock:	Elevation of the upper body, contact emergency physician
Cardiovascular arrest:	Immediate cardiopulmonary resuscitation, contact emergency physician

UNDESIRABLE EFFECTS

The measures which should be taken in the event of the occurrence of the following symptoms are described in the section "Therapy of overdose".

Due to the local anesthetic ingredient mepivacaine, the following side effects can occur from the use of MEPIVASTESIN:

Milder central nervous symptoms involve metallic taste, tinnitus, dizziness, nausea, vomiting, restlessness, anxiety, initial increase in respiratory rate.

More severe symptoms are drowsiness, confusion, tremor, muscle twitching, tonoclonic spasms, coma and respiratory paralysis.

Severe cardiovascular episodes are seen in the form of a drop in blood pressure, asequence, bradycardia, cardiovascular arrest.

Allergic reactions to mepivacaine are extremely rare.

INFORMATION CONCERNING STORAGE AND STABILITY

Keep out of the reach of children!

Do not use the preparation after the expiry date stated on the bottom of the tin and the cartridges.

Store in the original package in order to protect from light.

Do not store above 25°C.

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07/2012