

MEDICAINE® 3% without vasoconstrictor

PHARMACEUTICAL FORM:

Injectable solution box of 50 cartridges of 1.8 ml.

COMPOSITION PER CARTRIDGE:

Mepivacaine hydrochloride 54 mg
Excipients : Sodium chloride 5.4 mg
W.F.I. q.s.f. 1.8 ml

PHARMACOLOGICAL CLASS:

Local anaesthetic for dental use.

THERAPEUTIC INDICATIONS:

This drug is indicated for adult and child over 4 years, in Cased of:

- Local or local-regional anaesthetic for stamatalogical use. recommended for any intervention, especially on people with serious hypertension coronary problems and who are diabetic.
- This anaesthesia will be also selected for the patients at whom the use of vasoconstrictor is contraindicated.
- All infiltration or conduction anaesthesia.
- All classical intervention, even delicate and prolonged.

CONTRAINDICATIONS :

Know allergy to local anaesthetics of the same chemical group.

CONTRAINDICATIONS DUE TO MEPIVACAINE HYDROCHLORIDE :

- Serious myasthenia,
- Low cholinesterase plasma levels,
- Serious hepatic problems: cirrhosis, genetic or acquired porphyria.

WARNING :

- intravascular injection is strictly contraindicated : it is therefore imperative to ensure that the needle used for the Injection does not enter a vessel.

- Toxic reactions may appear In the event of an overdose or accidental intravenous injection.

- Do not mix the injectable solution with other product in the same syringe

- Opened cartridges must not be reused.

- wearing gloves is recommended (WHO and FDA) in dentistry in order to eliminate the risk of contact allergy by the dentist.

- A transitory whitening of the mucous membranes apposite to the injection area could appear.

PRECAUTIONS OF USE :

- It is highly recommended that the patient be questioned in order to know the field, current therapies and possible history of allergies.

- The use of this drug during pregnancy should be allowed only if it's necessary.

- Each time a local anaesthetic is used, the following must be available.

- Anti-convulsion drugs, muscle relaxants, atropine and vasopressors: resuscitation equipment (particularly source of oxygen) permitting artificial ventilation if it becomes necessary.

- In case of elevated doses, pre-treat with a benzodiazepine.

- These products should be used with caution in patients with a severe cardiac disease, severe anaemia or circulatory defect, regardless of the cause.

- Local anaesthetics should be avoided in infected or inflammatory areas.

- The risk of anesthesiophagy should be taken into consideration: various bites, lips, mucous membranes, tongue. Inform the patient avoid chewing gum or food so long as the mouth and throat remain desensitized.

- As for each cartridge, the diaphragm must be disinfected just prior to use.

It must be very carefully dabbed either with 70% ethyl alcohol or pure 90% isopropyl alcohol for pharmaceutical use.

- The cartridges must not, under any circumstances, be immersed in any solution.

MEDICAL INTERACTIONS AND OTHER INTERACTIONS:

Antiarrhythmic, namely: tocainide, digitalis preparations.

Cimetidine.

Antimyasthenics: The use of local anesthetics by neuronal transmission may thwart the effects of antimyasthenics on the skeletal muscles, especially if large amounts are quickly absorbed. The temporary adjustment of antimyasthenic doses may be necessary in order to control possible symptoms of myasthenia gravis, an improbable effect in doses used in odontostomatology.

Disinfectant solution containing heavy metals:

- Risk of local irritation such as swelling, edema

- Do not use for disinfecting mucous membrane before administering a local anaesthetic.

ADVERSE EFFECTS :

Toxic reactions (due to an abnormally high concentration of local anesthetic in the blood) may either appear immediately, by accidental intravascular injection, or later, by a true overdose following the injection of an excessive amount of anesthetic solution.

The following may be observed :

- Symptoms due to effects on the central nervous system:

nervousness, headaches, nausea and vomiting, tremors, drowsiness, loss of consciousness, convulsions and respiratory failure.

Cardiovascular signs: hypertension, bradycardia, cardiovascular collapse, cardiac arrest.

The subjects with risks are those with a cardio-vascular affection or those affected with thyrotoxicose.

DOSAGE AND MODE OF ADMINISTRATION:

Adults:

- For common intervention :

1 to 3 cartridges of Medicaïne 3% can be used per intervention based on the size of the area to be anesthetized and the injection technique used.

• The operation is rarely repeated more than once per week on the same patient.

Children:

- The amount injected should be determined based on the child's age and the extent of the intervention. The child's weight must be taken into consideration.

- The average dose to be used is 0.025 ml of anaesthetic solution per kilogram of weight

- The total dose must not exceed one cartridge per session.

- The maximum dose in mg of mepivacaine hydrochloride to be administered in a child is as follows:

weight of the child (expressed in kilograms) x 1,33.

OVERDOSAGE:

Manifestations of neurological toxicity are treated, if clonic convulsions appear, by:

• Hyperventilation.

• Lying the patient down, if required.

- The intravenous injection of a barbiturate with a short action time or an intramuscular injection of a benzodiazepine

• Oxygenation

• Assisted ventilation.

DELIVERY CONDITIONS:

List II, only for professional use in dentistry.

PARTICULAR CONDITIONS OF PRESERVATION:

Store at a temperature below 30°C and away from light.

Avoid all risk of freezing.

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PRESENTATION AND M.A. NUMBER:

Product	Presentation	M.A.number
MEDICAINE 3%	Box of 50 cartridges of 1.8 ml	923 301 2

This is a Medicament

- Medicament is a product but not like the others.

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicine its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed for you.

- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children

