

Medicaïne® 2%

Solution for injection

Mepivacaine hydrochloride and Epinephrine bitartrate

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your dentist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your dentist, doctor or pharmacist.

In this leaflet:

1. What MEDICAÏNE 2% is and what it is used for?
2. Before you use MEDICAÏNE 2%?
3. How to use MEDICAÏNE 2%?
4. Possible side effects.
5. How to store MEDICAÏNE 2%?
6. Further informations.

1. What MEDICAÏNE 2% is and what it is used for?

MEDICAÏNE 2% is given by injection to cause loss of feeling before and during dental procedures.

It contains two active ingredients:

- Mepivacaine hydrochloride, a local anaesthetic which prevents pain.
- Epinephrine bitartrate, a vasoconstrictor which makes the effect last longer. Epinephrine narrows the blood vessels at the site of injection, which keeps the anaesthetic where needed for a longer time. It also controls the bleeding during the surgery.

MEDICAÏNE 2% is for children over 4 years old and adults.

Only a dentist can administer this product.

2. Before you use MEDICAÏNE 2%

Do not use MEDICAÏNE 2%

- If you are allergic (hypersensitive) to one of the active ingredients (Mepivacaine hydrochloride or Epinephrine bitartrate) or to any of the other ingredients (refer to section 6).
- If you are allergic to local anaesthetics
- If you are asthmatic or have suffered difficulty with your breathing as a result of taking medicines which contain ingredients called sulphites or metabisulphites.
- If you have a high blood pressure (arterial hypertension),
- If you have particular heart or blood vessels disease (coronary or valvular cardiac disease),
- If you are taking or have taken medicines for depression in the last two weeks,
- in children under 4 years old.

Take special care with MEDICAÏNE 2%:

Before receiving this medicine, tell your dentist if:

- You have problems with your heart or blood vessels,
- You have problems with your liver,
- You have problems with your kidneys,
- You have a severe infection or an inflammation in the area where the injection will be done,
- You are epileptic,
- You have troubled breathing.

Using other medicines:

- Please tell your dentist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Do not use MEDICAÏNE 2% if you are taking or have taken medicines for depression in the last two weeks.

Your dentist should take special attention if you are taking the following medicines:

- Medicines used to reduce your blood pressure (e.g. betablockers like propranolol or vasopressor drugs like dihydroergotamine),
- Medicines used to reduce patient apprehension (e.g. sedatives). In that case, the dosage of anaesthetic should be reduced.
- Medicines used to treat some psychiatric disorders called phenothiazines.
- Medicines used for anaesthesia (e.g. chloroform, halothane, cyclopropane, trichloroethylene).

Pregnancy and breast-feeding:

This medicine should be used with caution during pregnancy or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

If you experience side effects, including dizziness or blurred vision, you should not drive or operate machinery until these effects have disappeared.

Important informations about some ingredients of MEDICAÏNE 2%

MEDICAÏNE 2% contains:

- Sodium metabisulphite: it may rarely cause severe allergic reactions and difficulty in breathing (bronchospasm).

3. How to use MEDICAÏNE 2%?

Your dentist will explain to you why you are being treated with

MEDICAÏNE 2%.

He or she will choose the formula and adjust the dosage according to your age, your health and the dental procedure. One cartridge is usually sufficient but your dentist may give you a greater quantity.

MEDICAÏNE 2% is injected between two teeth.

If your dentist uses more MEDICAÏNE 2% than he or she should

If you think you may have been given too much of this injection and feel unwell (see section 4, possible side effects), tell your dentist.

4. Possible side effects:

Like all medicines, MEDICAÏNE 2% can cause side effects, although not everybody gets them. While you are in your dentist's office, your dentist will carefully follow the effects of MEDICAÏNE 2%.

Administration of MEDICAÏNE 2% may cause high plasma levels in active substances (Mepivacaine and/or Epinephrine), especially overdose or unintended injection.

Symptoms include: effects on your senses (hearing, sight, behaviour), effects on your heart or blood vessels, effects on your immune defences (diminished tolerance).

As complications to the manifestations of progressive cerebral hypoxia (decrease below normal levels of oxygen in tissue) and seizure or cardiovascular problem, sweating, feeling of faintness, changes in pulse or sensorium, vasovagal reaction might occur. The stimulation of the senses due to adrenaline appears by increasing fear and anxiety, tension, restlessness, throbbing, headache, tremor, weakness, pallor, respiratory difficulty.

The following common side effects affect between 1 and 10 of every 100 patients treated:

Failure of cardiac circulation (cardiovascular collapse) which may lead to cardiac arrest, loss or abnormality of rhythm (arrhythmia or dysrhythmia), conduction disorders, drop in blood pressure (hypotension), convulsions, feeling of well-being commonly exaggerated (euphoria), unconsciousness, malaise, confusion, dizziness, headache; if you are in an upright position, a vasovagal reaction (relating to the action of the nerve upon the blood vessels) may develop, slow or rapid heartbeats (bradycardia or tachycardia), irregular pulsation of heart (palpitations), lightheadedness, feeling nervous (nervousness), apprehension, agitation, drowsiness, buzzing in the ears (tinnitus), blurred or double vision, nausea, vomiting, sensations of heat, cold or numbness, uncontrolled eye movement (twitching), trembling.

The following common side effects affect between 1 and 1000 of every 10,000 patients treated:

- Abnormality of rhythm of ventricle (ventricular fibrillation)
The following very rare side effects affect 1 of 10,000 patients treated:
- Severe allergic reactions (anaphylactoid reactions) characterized by swelling of the face, lips and/or tongue, difficulty breathing. These allergic-type reactions may occur in patients with bronchial asthma due to hypersensitivity to sulphites (see section "Important information about some ingredients of MEDICAÏNE 2%").
- Allergic reactions characterized by skin rash (cutaneous lesions), eruption of itching wheals (urticaria), swelling (edema).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your dentist, doctor or pharmacist.

5. How to store MEDICAÏNE 2%?

Keep out of the reach and sight of children.

It is most unlikely that you will be asked to look after this medicine. Your dentist will not use this medicine after the expiry date which is stated on the package.

The expiry date refers to the last day of that month.

Store in a temperature below 25°C and keep away from light. Avoid any risk of freezing.

6. Further informations:

What MEDICAÏNE 2% contains?

- Active substances: Mepivacaine hydrochloride, Epinephrine bitartrate
- The other ingredients are: sodium metabisulphite, sodium chloride, Hydrochloric acid, sodium Hydroxide and water for injection.

What MEDICAÏNE 2% looks like and content of the pack

It is a solution for injection.

MEDICAÏNE 2% is available in boxes containing 50 cartridges of 1.8 ml in clear colorless glass vial with rubber stopper.

Marketing authorization holder & Manufacturer

Les Laboratoires MédiS
KM7 route de Tunis, BP 206
8000 Nabeul,
Tunisia

This Leaflet was last revised on February/2015

This is a Medicament

- 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, their 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

Council of Arab Health Ministers
Union of Arab Pharmacists

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