Read this leaflet carefully before taking the medicine.
- Keep this leaflet. You may need to read it again.
- If you have any question, consult your doctor or your pharmacist.
- This medicine has been prescribed to you personally and you must not give it to others. It can harm them, even if the symptoms are the same as yours.

In this leaflet

DILOCAIN® 2%
INJECTABLE SOLUTION

The active components are lidocaine and epinephrine. Each ml of the solution contains 20 mg of lidocaine hydrochloride and 0.0125 mg of epinephrine (bitartrate).
The excipients are: sodium metabisulfite (E-223), sodium chloride and water for injection.

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1. WHAT DILOCAIN® 2% INJECTABLE SOLUTION IS AND WHAT IT IS USED FOR

DILOCAIN® 2% is an injectable solution. It is presented in a cylindrical ampoule, in packages containing 100 ampoules.
DILOCAIN® 2% is indicated in local dental anesthesia, by infiltration or nerve block.

2. BEFORE YOU USE DILOCAIN® 2% INJECTABLE SOLUTION

- **Do not use DILOCAIN® 2% INJECTABLE SOLUTION:**

- If you are allergic to lidocaine, epinephrine, amide type local anesthetics or to any of the other components of the formulation.
- If you have a closed-angle glaucoma (increase of the intraocular pressure), paroxysmal tachycardia (rapid pulse) or complete high frequency arrhythmia (change of cardiac rhythm).
- Do not administer it intravenously.

- **Take special care with DILOCAIN® 2% INJECTABLE SOLUTION:**

- If you have any liver disorder. If the disorder is severe, a special precaution must be taken, since toxic concentrations of lidocaine can be reached.
- If you have a renal disease, since the anesthetic or its derivatives can accumulate.
- If you are being treated with monoamine oxidase inhibiting drugs, tricyclic antidepressants or phenothiazines, and if you are undergoing treatment with noncardioselective beta-blockers.
- If you suffer from a cardiovascular dysfunction, since the cardiac depressant effects can increase.
- If you are sensitive to drugs, especially to anesthetics or other chemically related components.

Avoid injection in an inflamed or infected area.
Ask your doctor, even if any of the previously mentioned events had occurred to you at some time.

- **Pregnancy:** Ask your doctor or pharmacist before using any medicine. Precaution must be taken when prescribed to pregnant women.

- **Lactation:** Ask your doctor or pharmacist before using any medicine. Lidocaine is excreted in maternal milk in small amounts. Problems during lactation have not been reported.

- **Driving and using machines:** Although the effects on ability to drive vehicles are not expected, the dentist will decide when are you able to drive and handle machinery.

- **Important information about some of the components of DILOCAIN® 2% INJECTABLE SOLUTION:** This medicinal product contains sodium metabisulfite (E-223) as excipient, due to which it can cause allergic-type reactions, including anaphylactic reactions and bronchial spasm in susceptible patients, especially in those with history of asthma or allergies.
Athletes must take into account that lidocaine can produce a positive result in drug tests.

- **Use of other medicinal products:** Inform your doctor or pharmacist if you are taking or have recently taken any other medicinal product, even those not prescribed. Some drugs can influence the action of others.

The administration with the following medicinal products is not recommended:
- Tricyclic antidepressants or (MAO) monoamine oxidase inhibitors: they can increase the vasodepressive effect of epinephrine.
- Phenothiazine and butyrophenone: they can reduce or revert the vasodepressive effect of epinephrine.
- Non-cardioselective beta-blocker drugs (for example, propranolol).
- Central nervous system depressants: additive depressant effects can take place.
- Disinfectant solutions containing heavy metal iones: lidocaine releases the iones of these solutions, being able to cause a great local irritation and swelling.
- Neuromuscular blockers: the anesthetic can prolong or enhance the action of this kind of drugs. Intramuscular injection of lidocaine can cause an increase in phosphokinase levels.

3. HOW TO USE DILOCAIN® 2% INJECTABLE SOLUTION

Follow these instructions unless your doctor has given you different indications.
Remember to take your medicinal product.
Your doctor will indicate the appropriate dose and duration of your treatment with DILOCAIN®.
Do not suspend the treatment before indicated.
If you have the impression that the effect of this medicinal product is too strong or too weak, talk to your doctor or pharmacist.
In infiltrations or terminal anesthesia, the administration of 1 ml of DILOCAIN® is usually sufficient.
In nerve anesthesia, the dose will be 1.5-2 ml. The maximum dose in 24 hours is 500 mg of lidocaine, and it must not in any case exceed 7 mg/kg of body weight in adults.
Do not ingest food until sensitivity is re-established.

- **If you take more DILOCAIN® 2% INJECTABLE SOLUTION than you should** immediately consult your doctor or pharmacist. Respiratory and circulatory complications and convulsions can occur. If they occur, the administration will be interrupted and the appropriate treatment will be established.

4. POSSIBLE SIDE EFFECTS

Like all medicinal products, DILOCAIN® 2% can have side effects.
Common (>1/100, <1/10): excitation, agitation, dizziness, tinnitus (ringing in the ears), blurred vision, nausea, vomiting, tremors and convulsions. After excitation, respiratory depression and coma, even with myocardial depression, hypotension, bradycardia, arrhythmia, and heart failure may occur. **Very rare** (<1/10.000):
Allergic reactions.
Other side effects: Epinephrine can cause, although extremely rarely, tachycardia, cardiac rhythm disorders and increased blood pressure.
If you notice any side effects or any other reaction not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORAGE OF DILOCAIN® 2%INJECTABLE SOLUTION

Keep DILOCAIN® 2% out of the reach and sight of children.
Do not store above 30ºC and store protected from light. Freezing should be avoided.
Expiry: Do not use DILOCAIN® 2% after the expiry date indicated on the package.

6. INSTRUCTIONS FOR THE SANITARY PERSONNEL

To avoid an intravenous injection, an aspiration must always be carried out prior to the injection. Usage of the appropriate injection syringe for the infiltration anesthesia ensures perfect functioning, as well as maximum safety against the breakage of the cylindrical ampoules. Only the contents of intact ampoules should be injected.
In order to avoid any risk of infection (for example, prevention of hepatitis transmission) it is essential to use recently sterilized syringes and needles. You must not administer the remaining contents of partially used cylindrical ampoules to other patients.
For the exterior disinfection of the cylindrical ampoules, 91% isopropyl alcohol or 70% ethyl alcohol without denaturants are recommended. Solutions containing heavy metals are not recommended, since they release iones (mercury, zinc, copper, etc.), which cause edemas in local dental anesthetic injections.
Injection in an inflamed area must be avoided.