Lidocaine 10 mg/ml solution for injection

**Summary**

- **Product type**: Injection
- **Active substance**: Lidocaine hydrochloride monohydrate Ph
- **Strength**: 10 mg/ml
- **Pack sizes**: 5 ml and 50 ml
- **Uses**: Producing local anaesthesia
- **Side effects**: May cause dizziness, nausea, or light-headedness

**Ingredients**

- Sodium (as sodium chloride) 20.8 mg per 10 ml ampoule (2.08 mg/ml)
- Sodium chloride 10.4 mg per 5 ml ampoule (2.08 mg/ml)

**Description**

- A clear, colourless or slightly yellowish liquid, free from visible particles.

**Packaging and storage**

- Each ml of solution for injection contains lidocaine hydrochloride monohydrate Ph.
- Do not use this medicine after the expiry date which is stated on the label.
- It does not require any special storage conditions.

**Side effects**

- **Common**: Dizziness, nausea, or light-headedness.
- **Uncommon**: Convulsions and cardiac arrhythmias.
- **Rare**: Anaphylactic shock.

**Warnings and precautions**

- **Contraindications**
  - In patients with a known sensitivity to Lidocaine Hydrochloride.
  - In patients with cardiovascular disease.
  - In patients with a history of seizures.
  - In patients with severe liver or kidney disease.
  - In patients with a history of methemoglobinemia.

**Method of administration**

- Intravenous injection: 1 to 2 mg/kg body weight or 1 to 2 mg/ml.
- Spinal injection: 3 to 5 mg/kg body weight or 3 to 5 mg/ml.
- Epidural injection: 1 to 2 mg/kg body weight or 1 to 2 mg/ml.

**Dosage and administration**

- The dose depends on the extent of the operation.
- The anaesthesia technique should be selected carefully.
- The doses are reduced to children and patients with poor general condition.

**Interactions**

- The other ingredients are sodium chloride and water for injection.

**Further information**

- The following information is intended for medical or healthcare professionals.
- Patients should be given an information leaflet before they are given Lidocaine.

**4. Possible side effects**

- The doctor treating you is trained to deal with serious side effects from getting too much Lidocaine.
- If you have any further questions, ask your doctor, pharmacist or nurse.

**5. How to store the medicine**

- Keep the bottle tightly closed.
- Store the medicine in a cool place.
- Do not refrigerate.

**6. Contents of the pack and other information**

- Sacral surgery analgesia 10 mg/ml 40 ml 400 mg
- Intravenous regional anaesthesia: 10 mg/ml 0.5 ml 0.5 mg
- Small procedures 10 mg/ml 2-10 ml 20-100 mg

**7. Manufacturer**

- Manufacturer: [manufacturer name]

**8. Further information about the medicine**

- If you are already taking one of these medicines, speak to your doctor before you are given this medicine.
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.
- You should only be used during pregnancy and breast-feeding if absolutely necessary.
- If you are already taking one of these medicines, speak to your doctor before you are given this medicine.
Lidocaine 20 mg/ml solution for injection

**Use**

For infiltration, nerve block and regional analgesia.

**Posology**

- **Adults**
  - The average dose to be used is in the range of 20 mg to 30 mg lidocaine per kg of body weight. The maximum dosage is 400 mg.
  - In adults with severe burns, the lidocaine dose should be limited to 5 mg/kg.
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- **Children**
  - The maximum dosage for children (1 to 12 years of age) is 5 mg/kg.
  - The dose should be adjusted according to age, weight and condition of the patient.

**Contraindications**

- Lidocaine must not be given to patients with known hypersensitivity to lidocaine or to local anaesthetics of the amide type, or those with a history of angioedema or asthma caused by a previous dose of lidocaine or other local anaesthetics.

**Special precautions**

- Painful anaesthesia techniques should be avoided. The behaviour of the child during treatment has to be monitored carefully.
- Special care has to be exercised when treating children below 4 years. The quantities may need to be reduced.
- The doses are reduced to children and patients with poor general condition.
- Lidocaine Injection is not recommended for use in neonates (see section 5.2).

**Preparation of solution**

- The average dose to be used is in the range of 20 mg to 30 mg lidocaine per kg of body weight. The maximum dosage is 400 mg.

**Method of administration**

- Lidocaine 10 mg/ml should be administered slowly (may take up to 1 minute).
- Lidocaine 20 mg/ml should be administered slowly (may take up to 2 minutes).

**Substance**

- Each 1 ml of solution contains 20 mg of lidocaine hydrochloride.
- Sodium (as sodium chloride) 20.8 mg per 10 ml ampoule (2.08 mg/ml)
- Excipients: Sodium (as sodium chloride) 28 mg/ampoule (2.8 mg/ml)

**Adverse reactions**

- **Uncommon (affects less than 0.1% of people)**
  - **Cardiac arrhythmia**
  - **Seizures**
  - **Loss of consciousness**
  - **Visual disturbances**

- **Other possible side effects:**
  - Severe itching of the skin (with raised lumps), swelling of the face, tongue and throat, low blood pressure.

**Interaction**

- **Other medicines used to treat viral infection** (e.g. amprenavir, atazanavir, darunavir) should be avoided if possible.

**Overdose**

- The first signs of being given too much Lidocaine are usually as follows:
  - **Drowsiness**
  - **Loss of consciousness**
  - **Visual disturbances**

**Prevention of side effects**

- **Keep this leaflet. You may need to read it again.**
- **Read all of this leaflet carefully before you are given this medicine because it contains important information about your medicine.**

**Dosage and Administration**

- By injection of the solution into or around the area of operation. It may also be used to produce local anaesthesia when pain is expected.

**Product information**

- **Lidocaine 20 mg/ml solution for injection**
  - **Pack size:** 20 x 5 ml, 20 x 10 ml
  - **Manufacturer:** LABORATORIOS NORMON, S.A.
  - **Dublin 2
  - **Date:** 23/03/17
  - **Review:** 1

**Reporting of side effects**

- **If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any other medicines you are taking, any foods you are eating and any other health problems you may have.**

**Healthcare professionals**

- If you have any further questions on the use of this product, ask your doctor.

**Side effects**

- **Common (affects more than 1 in 10 people)**
  - **Dizziness**
  - **Nausea**
  - **Signs of being given too much Lidocaine.**

- **Rare**
  - **Hypersensitive reactions such as hives (urticaria), rash, angioedema and in more severe cases, anaphylactic shock**

- Other possible side effects:
  - **Severe itching of the skin (with raised lumps)**

**Pharmacological classification**

- **Lidocaine**
  - **Systemic anti-inflammatory drug**
  - **Local anaesthetic**
  - **Class of medicines:** amide type local anaesthetics

**Summary of product characteristics**

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