93865-LIDOCAINE HCL

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation

Name: Lidocaine hydrochloride
Bulk code: 93865

1.2 Synonyms

Lidocaini hydrochloridum; Lignocaine hydrochloride; Xylocaine hydrochloride; Lidocaine hydrochloride.

2. DESCRIPTION

Appearance: Crystalline powder.
Colour: White.
Smell: Odourless

3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: $C_{14}H_{22}N_2O$, ClH, H_2O
CAS:13647-35-3
Molecular 6108-05-0 (monohydrate form)

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

Solubility: Soluble in 0.7 p. water, 1.5 p. alcohol and 40 p. chloroform; practical insoluble in ether.

Melting point: 74-79ºC

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

Approximately 1.23 g of monohydrate lidocaine hydrochloride or 1.16 g of lidocaine hydrochloride anhydrous are equivalent to 1 g of lidocaine base.

This is an amide local anaesthetic with an intermediate duration that acts by stabilising the neuronal membrane, preventing the start and propagation of the nerve impulse It is used as a topical local anaesthetic and in skin conditions like itching and pain associated with

wounds, burns, abrasions, skin manifestations of systemic diseases like measles, bites, eczema, etc. of mucous membranes, in organic explorations of the mouth, larynx, noise, respiratory, upper digestive and urinary tracts, and in anal and vulvar itching and haemorrhoids.

6. DOSAGE.

No information available

In gel format, it is used for anaesthesia in the urinary tract. In women, it is used at an amount equivalent to 60-100 mg of lidocaine hydrochloride, which is inserted inside the urethra several minutes before the examination; in men, the amount is equivalent to 100-200 mg, used before catheterisation, and 600 mg before probe and cystoscopy. A maximum of 600 mg lidocaine hydrochloride may be used in gel format in 12-hour periods.

Topical solutions are also used for surface anaesthesia of the mucous membranes of the mouth, throat and other mucosa in the upper gastrointestinal tract. For pain in the mouth and throat, 2% solutions are employed, using 5 ml (100 mg of lidocaine hydrochloride) in mouthwashes and swallowing it, or 15 ml (300 mg of lidocaine hydrochloride) in mouthwashes and spitting it out; for pharyngeal pain, it is used in a solution that is gargled then swallowed if necessary. The frequency between applications must be more than 3 hours. Doses of 10 ml (200 mg lidocaine hydrochloride) have been used to treat hiccups. Doses of 1-7.5 ml of a 4% solution (40-300 mg lidocaine hydrochloride) have been used prior to a bronchoscopy, bronchography, laryngoscopy, endotracheal intubation and biopsy.

7. REMARKS.

STORAGE:

Store at room temperature (25±2ºC), in a cool, dry place, away from sunlight, in a hermetically sealed container.

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

8. BIBLIOGRAPHY.

Pharmaceutical Monographs. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).