

Xylocaine ointment 5%

lidocaine

Ointment

Composition

Active constituent:

1 g Xylocaine ointment contains: Lidocaine base 50 mg

Therapeutic indications

Xylocaine ointment is indicated as topical anaesthesia for

- the alleviation of pain during examination and instrumentation, e.g. endotracheal intubation, proctoscopy, sigmoidoscopy, cystoscopy.
- dentistry: surface anaesthesia of the gums prior to injection and before deep scaling.
- anaesthesia of mucous membranes, e.g. various anal conditions such as haemorrhoids and fissures.
- temporary relief of pain associated with minor burns and abrasions of the skin, e.g. sunburn, herpes zoster and labialis, pruritus, sore nipples, insect bites.

Posology and method of administration

Lidocaine ointment is absorbed following application to mucous membranes or damaged skin, but probably only to a minimum extent when applied to intact skin. Absorption occurs most rapidly after intratracheal administration.

Following topical administration of lidocaine ointment in the oral mucosa, the onset of action occurs within 30 sec to 2 minutes. The onset on genital and anorectal mucosa is likely to occur within 5 minutes.

The duration of analgesia for burn wound pain and postoperative analgesia after circumcision is about 4 hours. The application of gauze over the cream may provide a slow release effect and prolonged duration in burn wounds.

As with any local anaesthetic the safety and effectiveness of lidocaine depend on the proper dosage, the correct technique, adequate precautions and readiness for emergencies.

The following dosage recommendations should be regarded as a guide. The clinician's experience and knowledge of the patient's physical status are of importance in calculating the required dose.

The ointment should be applied in a thin layer for adequate control of symptoms. A sterile gauze pad is recommended for application to broken and burned tissue.

Apply 1-2 g to tube prior to endotracheal intubation.

In dentistry, apply to previously dried oral mucosa. Allow at least 3-5 minutes for the anaesthesia to become effective.

For sore nipples, apply on a small piece of gauze. The ointment must be washed away before the next feed.

After a maximum endotracheal dose or application to mucous membranes the next dose should not be applied until 4 hours later. Not more than 20 g of the ointment should be administered in any 24-hour period to healthy adults. Xylocaine ointment can be used in the elderly without dose reduction. Xylocaine ointment should be used with caution in patients with traumatised mucosa. Debilitated or acutely ill patients, patients with sepsis, severe liver disease or cardiac failure, and children over 12 years of age weighing less than 25 kg should be given doses commensurate with their weight and physiological condition.

No plasma concentration data are available in children. Hence, for safety reasons, in children less than 12 years of age 100% bioavailability should be assumed following application to mucous membranes and broken skin, and a single dose should not exceed 0.1 g ointment/kg body weight (corresponding to 5 mg lidocaine/kg body weight). The minimum dosing interval in children should be 8 hours.

Contraindications

Known history of hypersensitivity to local anaesthetics of the amide type or to other components of the ointment.

Special warnings and special precautions for use

Excessive dosage of lidocaine or short intervals between doses can result in high plasma levels and serious adverse effects. Patients should be instructed to adhere strictly to the recommended dosage. The management of serious adverse reactions may require the use of resuscitative equipment, oxygen and other resuscitative drugs. (See Overdose).

Debilitated or acutely ill patients, patients with sepsis, severe liver disease or cardiac failure, and children over 12 years of age weighing less than 25 kg should be given doses commensurate with their weight and physiological condition.

Absorption from wound surfaces and mucous membranes is relatively high, especially in the bronchial tree. Xylocaine ointment should be used with caution in patients with traumatized mucosa and/or sepsis in the region of the proposed application.

Patients treated with anti-arrhythmic drugs class III (eg, amiodarone) should be kept under close surveillance and ECG monitoring considered, since cardiac effects may be additive.

When Xylocaine ointment is used in the mouth or throat area, the patient should be aware that the application of a topical anaesthetic may impair swallowing and thus enhance the danger of aspiration. Numbness of the tongue or buccal mucosa may increase the danger of biting trauma.

Interactions

With large doses of lidocaine, consideration should be given to the risk of additional systemic toxicity in patients receiving other local anaesthetics or agents structurally related to local anaesthetics, e.g. antiarrhythmics such as mexiletin and tocainide.

Specific interaction studies with lidocaine and anti-arrhythmic drugs class III (eg, amiodarone) have not been performed, but caution when treating patients is advised.

Drugs that reduce the clearance of lidocaine (eg, cimetidine or betablockers) may cause potentially toxic plasma concentrations when lidocaine is given in repeated high doses over a long time period. Such interactions should therefore be of no clinical importance following short term treatment with lidocaine (eg, Xylocaine ointment) at recommended doses.

Pregnancy and lactation

Pregnancy

It is reasonable to assume that a large number of pregnant women and women of child-bearing age have been given lidocaine. No specific disturbances to the reproductive process have so far been reported, e.g. no increased incidence of malformations.

Lactation

Like other local anaesthetics lidocaine may enter the mother's milk, but in such small amounts that there is generally no risk of this affecting the neonate.

Effects on ability to drive and use machines

Depending on the dose local anaesthetics may have a very mild effect on mental function and co-ordination even in the absence of overt CNS toxicity and may temporarily impair locomotion and alertness. With the recommended doses of lidocaine ointment adverse effects on the CNS are unlikely.

Undesirable effects

Reactions of an allergic nature (in the most severe instances anaphylactic shock) to amino-amide local anaesthetics are rare (<0.1%). The reactions are predominantly local contact sensitivity and are rarely systemic.

Skin irritation

Topical products that contain propylene glycol may cause skin irritation.

Overdose

Lidocaine can cause acute toxic effects if high systemic levels occur due to fast absorption or overdosage. With the recommended doses of Xylocaine ointment, toxic effects have not been reported.

However, should systemic toxicity occur, the signs are anticipated to be similar in nature to those following the administration of local anaesthetics by other routes.

Local anaesthetic toxicity is manifested by symptoms of nervous system excitation and, in severe cases, central nervous and cardiovascular depression.

Severe neurological symptoms (convulsions, CNS depression) must be treated symptomatically by respiratory support and the administration of anticonvulsive drugs.

Pharmacodynamic properties

Pharmacotherapeutic group: Local anaesthetic, ATC code N01BB02

Lidocaine is absorbed following application of Xylocaine ointment to mucous membranes and to damaged skin. It is inactive when applied to intact skin. Absorption occurs most rapidly after intratracheal administration. The onset of action is 3-5 minutes on mucous membranes.

Lidocaine, like other local anaesthetics, causes a reversible blockade of impulse propagation along nerve fibres by preventing the inward movement of sodium ions through the nerve membrane. Local anaesthetics of the amide type are thought to act within the sodium channels of the nerve membrane.

Local anaesthetic drugs may also have similar effects on excitable membranes in the brain and myocardium. If excessive amounts of drug reach the systemic circulation rapidly, symptoms and signs of toxicity will appear, emanating from the central nervous and cardiovascular systems.

Central nervous system toxicity usually precedes the cardiovascular effects as it occurs at lower plasma concentrations. Direct effects of local anaesthetics on the heart include slow conduction, negative inotropism and eventually cardiac arrest.

Preclinical safety data

In animal studies the toxicity noted after high doses of lidocaine consisted of effects on the central nervous and cardiovascular systems. No drug-related adverse effects were seen in reproduction toxicity studies, neither did lidocaine show a mutagenic potential in either in vitro or in vivo mutagenicity

tests. Cancer studies have not been performed with lidocaine, due to the area and duration of therapeutic use for this drug.

List of excipients

- Polyethylene glycol ointment
- Polyethylene glycol 3350
- Propylene glycol
- Water, purified

Shelf-life

Please see outer pack.

Special precautions for storage

Do not store above 25°C. Do not freeze.

Pack size

Please see outer pack.

Instructions for use, handling and disposal

The protective membrane of the tube is perforated when applying the cap.

The ointment can easily be removed from the site of application and from clothing by washing with water.

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