Xylonor gel

lidocaine, cetrimide

The following information is intended for healthcare professionals only:

For professional use by dentists and stomatologists only.

Posology:

For all populations, the lowest dose leading to effective anaesthesia should be used. The necessary dosage must be determined on an individual basis.

Adults

To be used only once from 0.1 to 0.5 g by topical local application with a cotton pellet. The recommended dose is 0.10 g to 0.20 g of gel (about the size of a small hazelnut) to cover an area of about 1 cm² to 2 cm², corresponding to 5 to 10 mg of lidocaine.
The maximum daily administration of the medicinal product should not exceed 4 g, equivalent to 200 mg of lidocaine.

Paediatric population (from 4 years of age)

The recommended dose is 0.10 g to 0.20 g of gel (about the size of a small hazelnut) to cover an area of about 1 cm² to 2 cm², corresponding to 5 to 10 mg of lidocaine.
The maximum daily administration for a paediatric population should not exceed 4 mg/kg of lidocaine.

Elderly patients or patients with hepatic function disorders

When liver activity is reduced, the minimum effective anaesthetic dose should be used when applied before anaesthetic injection.

Method of administration:

The medicinal product is for gingival use (local use) and can be occasionally used by oromucosal route.
Prior to use, the area of administration should be thoroughly dried.
Just before the procedure, a cotton bud should be impregnated with the medicinal product and applied on the mucosa.
Removal of excess saliva with cotton rolls or saliva ejector minimises dilution of the gel and permits maximum penetration.
Depending upon the surface to be anaesthetized and the status of the patient (age, physical condition), the dose of the gel used may be increased, up to 0.5 g.

Special warnings

Although the passage of lidocaine into systemic circulation is expected to be negligible, the medicinal product must be used with caution when applied to an inflamed or infected area due to the risk of a rapid systemic absorption of lidocaine.

Precautions to be taken before and after handling or administering the medicinal product:

- Saliva aspiration is required alongside isolation with a cotton bud of the site to be treated with the local anaesthetic.
- The risk of biting trauma (lips, cheeks, tongue) does exist but it is expected to be very low with the medicinal product due to the limited application area. When it is associated with injectable local anaesthetics, the patient should be told to avoid chewing gum or eating until sensation is restored.

Overdose

At normal doses and under normal conditions of administration, overdose is unlikely to occur with a product for local use only.

However, caution should be taken when using the product in association with injectable local anaesthetics, as the risk of CNS toxicity and cardiovascular toxicity may occur with high plasma levels of lidocaine due to excessive dosage, or rapid absorption.
To date, no cases of overdose have been reported when the topical products were used alone.

Symptomatology:

The following reactions may occur with high plasma levels of lidocaine due to excessive dosage or rapid absorption, in particular when associated with the use of injectable local anaesthetics:

Central Nervous System (CNS):
High plasma levels may cause CNS stimulation (including seizures) followed by CNS depression (including respiratory arrest) and may be characterized by the following signs and symptoms of escalating severity: circumoral paresthesia, light-headedness, nervousness, anxiety, apprehension, euphoria, confusion, dizziness, drowsiness, hyperacusis, tinnitus, blurred vision, vomiting, nausea, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. The excitatory manifestations (e.g., twitching, tremors, and convulsions) may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Cardiovascular System:
The cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, arrhythmia and cardiovascular collapse, which may lead to cardiac arrest. Hypertension, tachycardia and angina may be caused by concomitant use with an injectable local anaesthetic containing adrenaline.

Treatment of overdose:
The availability of resuscitation equipment should be ensured before the onset of dental anaesthesia with local anaesthetics.
If signs of acute toxicity are suspected, the medicinal product should be rinsed away immediately.
Oxygen should be administered rapidly, and assisted ventilation used if necessary. The patient's position should be changed to supine if necessary.
In cases of cardiac arrest, cardiopulmonary resuscitation should be immediately initiated.

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