SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Xylonor Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of gel contains 50 mg of lidocaine and 1.5 mg of cetrimide.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gingival gel

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Xylonor Gel is indicated for the production of topical anaesthesia in the buccal cavity, especially in the following procedures:

- Anaesthesia of the mucous membrane before injection, lancing of abscesses, or scaling.
- Surface anaesthesia for the extraction of mobile, deciduous or permanent teeth.
- Prevention of gagging during impression taking.
- Xylonor Gel is indicated in adults, and in children aged 4 to 18 years of age.

4.2 Posology and method of administration

Topical use only. Gingival use.

Posology:

To be used only once from 0.1 to 0.5 g by topical local application with a cotton pellet.

Method of administration:

Under aseptic conditions, extrude about 2 mm (equivalent to approximately 0.1 g) of gel from the tube onto a cotton pellet. Then massage previously dried 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.

Do not use in children under 4 years of age.

4.3 Contraindications

Hypersensitivity to the active substances, lidocaine and cetrimide, or to any of the excipients listed in section 6.1.

Hypersensitivity to local anaesthetics of the amide type.

4.4 Special warnings and precautions for use

The safety and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions and readiness for emergencies. The lowest dose that results in effective anaesthesia should be used to avoid high plasma levels and serious adverse effects. Debilitated, elderly patients, acutely ill patients and children should be given reduced doses commensurate with their age and physical status.

Xylonor Gel should be used with caution if there is sepsis or extremely traumatised mucosa in the area of application, since under such conditions, there is potential for rapid systemic absorption of both lidocaine and cetrimide.

It should be used with caution in persons with known drug sensitivities.

There is a risk of anesthesiophagia leading to bites (lips, jaws, tongue); patients should be advised to avoid chewing-gum or any type of food as long as the anaesthesia persists. It is recommended that the patient does not take any food before he has recovered sensitivity.

There is a possibility of positive results on doping tests performed on sportsmen.

4.5 Interaction with other medicinal products and other forms of interaction

Soaps and anionic surfactants are known to decrease the bactericidal activity of cetrimide.

4.6 Fertility, pregnancy and lactation

Pregnancy

Reproductive studies have been performed in rats and rabbits without evidence of harm to the animal foetus. However, the safe use of lidocaine in humans has not been established with respect to possible adverse effects upon foetal development. Careful consideration should be given to this fact before administering this drug to women of childbearing potential, particularly during early pregnancy.

Breast-feeding

Problems in humans have not been documented. However, risk-benefit must be considered.

4.7 Effects on ability to drive and use machines

Xylonor gel has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Systemic adverse reactions are extremely rare with lidocaine ointments. However, as with any local anaesthetic, adverse reactions may result from high plasma levels due to excessive dosage, or rapid absorption, or may result from hypersensitivity, idiosyncrasy or diminished tolerance.

Central nervous system reactions

CNS reactions are excitatory and/or depressant, and may be characterized by nervousness, dizziness, blurred vision and tremors, followed by drowsiness, convulsions, unconsciousness, and possibly, respiratory arrest. The excitatory reactions may be very brief or may not occur at all, in which case the first manifestations of toxicity may be drowsiness, merging into unconsciousness and respiratory arrest.

Cardiovascular system reactions

Cardiovascular reactions are depressant and may be characterized by hypotension, myocardial depression, bradycardia, and possibly, cardiac arrest.

Allergic reactions

Allergic reactions may occur as a result of sensitivity to local anaesthetics. Anaphylactoid type symptomatology and reactions, characterized by cutaneous lesions, urticaria, and edema, should be managed by conventional means. The detection of potential sensitivity by skin testing is of limited value.

At the concentrations used on the skin and mucous membranes (0.1-1%), cetrimide does not generally cause irritation, but some patients become hypersensitive to cetrimide after repeated applications.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

The normal application of Xylonor Gel according to its directions for use is very unlikely to result in an overdose. However, in the improbable case that symptoms of an overdose do occur, the procedure for treatment is described below.

Treatment of a patient with toxic manifestations consists of assuring and maintaining a patent airway, supporting ventilation with oxygen, and assisted or controlled ventilation (respiration) as required. This usually will be sufficient in the management of most reactions. Should a convulsion persist despite ventilatory therapy, small increments of anticonvulsive agents may

be given intravenously. Examples of such agents include benzodiazepine (e.g., diazepam), ultrashort acting barbiturates (e.g., thiopental or thiamylal), or a short acting barbiturate (e.g., pentobarbital or secobarbital). Cardiovascular depression may require circulatory assistance with intravenous fluids and/or vasopressors (e.g., ephedrine) as dictated by the clinical situation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Anaesthetics for dental use.

Pharmacotherapeutic group: Local anaesthetics, Lidocaine combinations; ATC code: N01BB52

Xylonor Gel contains two therapeutic agents:

1. Lidocaine stabilises the neuronal membranes and prevents the initiation and conduction of nerve impulses, thereby effecting local anaesthetic action. It does not contain a paramino group.
2. Cetrimide is an antiseptic of the quaternary ammonium group with both bactericidal and detergent properties.

It has bactericidal activity against gram-positive organisms but is less effective against some gram-negative organisms ; strains of Pseudomonas aeruginosa are particularly resistant.

Xylonor Gel combines both these ingredients in a non-irritant, water miscible excipient. This gel effects local topical anaesthesia.

The onset of action is 2 - 5 minutes.

The duration of anaesthesia is 30 - 60 minutes. This anaesthetic effect is complemented by a disinfectant action.

5.2 Pharmacokinetic properties

Lidocaine is metabolized mainly in the liver, and excreted via the kidneys.
Approximately 90% of lidocaine administered is excreted in the form of various metabolites, while less than 10% is excreted unchanged. The primary metabolite in urine is a conjugate of 4-hydroxy-2, 6-dimethylaniline.

Cetrimide penetrates into the superficial layer of the epidermis.
Absorption through the gastro-intestinal tract is poor ; more than 90 % of the dose ingested is excreted in the faeces.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin (E954)

Spearmint oil

Macrogol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 25ºC.

Store in a dry place.

Keep tube tightly closed.

6.5 Nature and contents of container

Aluminium tube with internal epoxy varnish and polyethylene screw cap containing 15 g of gel.

6.6 Special precautions for disposal

Always discard any unused portion taken from the tube. Tightly close after use.

7 MARKETING AUTHORISATION HOLDER

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