SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Xylonor Spray, 150 mg/g + 1.5mg/g, oromucosal spray, solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram of solution contains 150 mg of lidocaine and 1.5 mg of cetrimide.

Each actuation delivers approximately a dose of 10 mg of lidocaine and 0.1 mg of cetrimide

Excipient with known effect: this medicinal product contains 45.45 g of ethanol 96% per 100g of solution.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray, solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Xylonor Spray is indicated for the production of topical anaesthesia and disinfection of the mucous membrane in the buccal cavity, especially:

- before the performance of a local or nerve block injection,
- prior to the extraction of mobile, deciduous or permanent teeth,
- prior to the adjustment and fitting of crowns and bridges or the adjustment of bands in orthodontic treatments,
- prior to the lancing of sub-mucosal abscesses
- prior to scaling.

Xylonor Spray is indicated in adults, and in children and adolescents aged 6 to 18 years of age.

4.2 Posology and method of administration

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

The recommended dose is one actuation which delivers approximately 10 mg of lidocaine and covers an area of about 1 cm2.

The maximum daily administration should not exceed 20 actuations, equivalent to 200 mg of lidocaine.

Paediatric population (from 6 years of age)

The recommended dose is one actuation which delivers approximately 10 mg of lidocaine and covers an area of about 1 cm².

The maximum daily administration in the 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 oromucosal use (local use).

Prior to use, the area of administration should be thoroughly dried.

The tip of the nozzle should be placed at 2 to 4 cm from the area to be anaesthetised. This operation can be repeated in three different locations in the mouth during the same session.

4.3 Contraindications

- Hypersensitivity to lidocaine or cetrimide, or to any excipients listed in section 6.1.
- Hypersensitivity to any amide local anaesthetics.
- Children (under 6 years old), because of a risk of choking.

4.4 Special warnings and precautions for use

Although the passage of lidocaine into systemic circulation is expected to be negligible, the medicinal product must be used with caution 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.
- The oropharyngeal use of local anaesthetics should be avoided, since this can interfere with swallowing capacities, particularly in children and consequently lead to choking.

The accidental orientation of the anaesthetic toward the uvula (soft palate) or the pharynx may trigger a transitory paralysis of these areas and temporary discomfort to

the patient. This quickly disappears. To avoid choking and related issues, the product should not be applied to the back of the throat.

This medicine contains 606 mg of alcohol (ethanol 96%) in a maximum daily dose of 1.3 g of product which is equivalent to 45.45% (w/w). It may cause a slight burning sensation when exposed to open wounds.

4.5 Interaction with other medicinal products and other forms of interaction

Known interactions that usually occur with lidocaine (beta-blocking agents, inhibitors of CYP1A2, sedatives) are not expected to occur when the product is used locally on the oral mucosa. However, when the oral mucosa is injured, lidocaine may be released into the systemic circulation.

Additive interactions with other local anaesthetics:

Local anaesthetic toxicity is additive. This is not directly applicable in topical dental anaesthesia but may be a concern when associated with injectable anaesthetics in case of unintended intravascular injection or rapid systemic resorption, especially in children.

The total dose of all administered local anaesthetics should not exceed the lowest maximum recommended dose of each local anaesthetic.

4.6 Fertility, pregnancy and lactation

Pregnancy

The product is applied locally on gingival tissues. No effects during pregnancy are anticipated, since the systemic exposure to lidocaine is negligible. The product can be used during pregnancy.

Breastfeeding

The product is applied locally on gingival tissues. Lidocaine is excreted in human milk, but at therapeutic doses of the product, no effects on the breastfed newborns/infants are anticipated. The product can be used during breastfeeding.

Fertility

This drug is applied locally on gingival tissues. No effects on fertility are anticipated since the systemic exposure to lidocaine is negligible.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Summary of the safety profile

The adverse reactions following the administration of lidocaine/cetrimide are similar to those observed with other amide local anaesthetics. These adverse reactions are mainly local application site reactions and hypersensitivity reactions.

Systemic adverse reactions are extremely rare with topical lidocaine. However, they may result from high plasma levels due to excessive dosage, or rapid absorption (see section 4.9) particularly when associated with injectable local anaesthetics. Such reactions may also result from hypersensitivity, idiosyncrasy, or diminished tolerance.

Drowsiness following the administration of lidocaine is usually an early sign of high lidocaine plasma levels and may occur as a consequence of rapid absorption.

Serious adverse reactions are generally systemic.

Tabulated list of adverse reactions

The reported adverse reactions come from spontaneous reporting and the literature.

The frequency classification follows the convention: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and "not known" (cannot be estimated from the available data).

MedDRA System Organ Class	***Frequency***	***Adverse Reactions***
Immune System disorders	Rare	Hypersensitivity including anaphylactic shock
Nervous System disorders	Not known	Local hypoesthesia
Respiratory, thoracic and mediastinal disorders	Not known	Bronchospasm
Gastrointestinal disorders	Not known	Gingival ulceration Oral mucosal exfoliation
Skin and subcutaneous tissue disorders	Not known	Angioedema Erythema Face oedema Rash Pruritus Urticaria
General disorders and administration site conditions	Not known	Application site oedema Application site burn

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

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 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nervous System / Anaesthetics / Anaesthetics, local / Amides / lidocaine, combinations; ATC code: N01BB52

Xylonor Spray is a combination of:

- Lidocaine: an amide local anaesthetic. When applied to the oral mucous membrane, it provides surface anaesthesia by controlling the painful stimulation occurring in or just beneath the mucosa. The local anaesthetic effect of lidocaine occurs via a reversible blockade of nerve fibre impulse propagation.
- Cetrimide: a quaternary ammonium disinfectant with antiseptic properties. This action occurs via protein denaturation, enzyme inactivation and damage of bacterial membranes.

Lidocaine in combination with cetrimide has an onset of action of 2 to 5 minutes and a duration of 10 to 20 minutes.

The intended use dosage is unlikely to cause systemic toxicity, as it falls well below the concentrations associated with systemic toxicity.

5.2 Pharmacokinetic properties

Lidocaine:

Absorption: the results from published studies performed in patients using various topical lidocaine-based preparations applied to healthy oral mucosa show that measured serum lidocaine levels remain well below the toxic range (< 5 μg/mL). Studies evaluating plasma peak levels of lidocaine using topical lidocaine patches (23 mg) or lidocaine sprays (200 mg) have determined the peak level to be 0.016 μg/mL and 0.35 μg/mL, respectively.

Distribution: lidocaine is 60% to 80% bound to plasma protein, primarily to alpha-1-acid glycoprotein. Topical bioavailability averages 3%.

Biotransformation: lidocaine is principally metabolized in the liver by the cytochrome P450 system. Consequently, after a topical dose of lidocaine is applied to the oral mucosa, any swallowed fraction is significantly metabolized before entering into the systemic circulation. This accounts for the low plasma lidocaine concentrations following the intraoral administration of lidocaine.

Elimination: lidocaine and its metabolites are excreted by the kidneys, 90% as metabolites and 10% as unchanged drug. The elimination half-life of lidocaine following an intravenous bolus injection is typically of 100 minutes.

Cetrimide:

No pharmacokinetic information regarding cetrimide is available. As cetrimide is only to be used topically and at low concentrations, plasma concentrations are expected to be extremely low and therefore not clinically significant. Consequently, it can be extrapolated that systemic exposure to cetrimide is negligible.

5.3 Preclinical safety data
There are no additional non-clinical data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Saccharin (E954), Spearmint flavor, Dipropylene glycol, Ethanol at 96% (v/v)

6.2 Incompatibilities
Not applicable

6.3 Shelf life
3 years

6.4 Special precautions for storage
Store below 25°C

6.5 Nature and contents of container
Metered dose aerosol containing 36 g of solution

6.6 Special precautions for disposal
The nozzle should be fitted onto the pump before use.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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