SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Xyloproct 5%/0.275% Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition for: 100 g:
Lidocaine 5 g
Hydrocortisone Acetate micro Ph. Eur. 0.275 g

Excipients with known effect:
Cetyl alcohol (7.4 g per 100 g of ointment)
Stearyl alcohol (0.9 g per 100 g of ointment)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Xyloproct rectal ointment is indicated in adults and children of all ages for the relief of symptoms such as anal and peri-anal pruritus, pain and inflammation associated with haemorrhoids, anal fissure, fistulas and proctitis. Pruritus vulva.

4.2 Posology and method of administration

Route of administration: Topical.

To be applied several times daily according to the severity of the condition. For intrarectal use, apply the ointment with the special applicator. Cleanse the applicator thoroughly after use.

A daily dose of 6 g ointment is well within safety limits. The duration of treatment may vary between ten days and three weeks. If the treatment is prolonged, a free interval can be recommended, especially if it is suspected that irritation due to lidocaine or hydrocortisone has occurred. If the local irritation disappears after the cessation of treatment, the possibility of sensitivity to lidocaine or hydrocortisone can be investigated, e.g. by a patch test.

Older people
Debilitated or elderly patients should be given doses commensurate with their age, weight and physical condition.

Paediatric population
Children should be given doses commensurate with their age, weight and physical condition.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 or to local anaesthetics of the amide type. Use on atrophic skin. Xyloproct Ointment should not be used in patients with untreated infections of bacterial, viral, pathogenic fungal or parasitic origin. Xyloproct should not be used by patients being treated with a class III anti-arrhythmic drug outside of hospital (see sections 4.4 and 4.5).

4.4 Special warnings and precautions for use

Xyloproct is intended for use for limited periods. Excessive dosage of lidocaine or short intervals between doses, may result in high plasma levels of lidocaine and serious adverse effects. Patients should be instructed to strictly adhere to recommended dosage.

Hospitalised patients treated with anti-arrhythmic drugs class III (e.g. amiodarone or sotalol) should be kept under close surveillance and ECG monitoring considered, since cardiac effects may be additive (see sections 4.3 and 4.5).

Appropriate antibacterial, antiviral or antifungal therapy should be given with Xyloproct if infection is present at the site of application.

The possibility of malignancy should be excluded before use.

If irritation or rectal bleeding develops treatment should be discontinued.

When using the special applicator, care should be taken to avoid instillation of excessive amounts of Xyloproct Ointment into the rectum. This is of particular importance in infants and children.

Systemic absorption of lidocaine may occur from the rectum, and large doses may result in CNS side-effects. On rare occasions convulsions have occurred in children.

Prolonged and excessive use of hydrocortisone use may produce systemic corticosteroid effects or local effects such as skin atrophy. With the recommended dosage systemic effects of hydrocortisone are unlikely.

Xyloproct ointment is possibly porphyrinogenic and should only be prescribed to patients with acute porphyria when no safer alternative is available. Appropriate precautions should be taken for vulnerable patients.

Xyloproct contains cetyl alcohol and stearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

Lidocaine should be used with caution in patients receiving anti-arrhythmic drugs, local anaesthetics or agents structurally related to local anaesthetics, since the toxic effects of these compounds are additive (see sections 4.3 and 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy
Xyloproct should not be used during pregnancy unless considered essential by the physician.

Breast-feeding
Lidocaine and hydrocortisone acetate are excreted into breast milk, but at therapeutic doses of Xyloproct, effects on the breastfed newborns/infants are unlikely.

Fertility
There is no fertility data available.

4.7 Effects on ability to drive and use machines

Xyloproct has minor influence on the ability to drive and use machines. Depending on the dose local anaesthetics may have a very mild effect on mental function and coordination even in the absence of overt CNS toxicity and may temporarily impair locomotion and alertness. With the recommended doses of Xyloproct adverse effects on the CNS are unlikely.

4.8 Undesirable effects

Contact sensitivity to lidocaine has been reported after perianal use. Contact sensitivity may also occur after the use of topical hydrocortisone.

In extremely rare cases amide-type local anaesthetic preparations have been associated with allergic reactions (in the most severe instances anaphylactic shock).

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 Yellow Card Scheme website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Systemic absorption of lidocaine may occur from the rectum. When using the special applicator care should be taken to avoid instillation of excessive amounts of Xyloproct Ointment into the rectum.

Lidocaine can cause acute toxic effects if high systemic levels occur due to rapid absorption or overdosage. With the recommended doses of Xyloproct, toxic effects have not been reported. On rare occasions convulsions have occurred in children following administration of overdose.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Hydrocortisone; ATC code: C05A A01

Lidocaine exerts a local anaesthetic effect by stabilising the neural membrane and preventing the initiation and conduction of nerve impulses.

Hydrocortisone acetate belongs to the mild group of corticosteroids and is effective because of its anti-inflammatory and anti-pruritic action.

5.2 Pharmacokinetic properties

The onset of action of lidocaine is 3 - 5 minutes on mucous membranes. Lidocaine can be absorbed following application to mucous membranes with metabolism taking place in the liver. Metabolites and unchanged drug are excreted in the urine.

Absorption of hydrocortisone may occur from normal intact skin and mucous membranes. Corticosteroids are metabolised mainly in the liver but also in the kidney, and are excreted in the urine.

5.3 Preclinical safety data

Lidocaine and hydrocortisone acetate are well established active ingredients.

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.

Genotoxicity tests with lidocaine showed no evidence of mutagenic potential. A metabolite of lidocaine, 2,6-xylidine, showed weak evidence of activity in some genotoxicity tests. The metabolite 2,6-xylidine has been shown to have carcinogenicity potential in preclinical toxicological studies evaluating chronic exposure. Risk assessments comparing the calculated maximum human exposure from intermittent use of lidocaine, with the exposure used in preclinical studies, indicate a wide margin of safety for clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Zinc oxide
Aluminium acetate
Stearyl alcohol
Cetyl alcohol
Water purified
Macrogol (3350 and 400)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years when stored between 2°C and 8°C.
2 months when stored below 25°C.

6.4 Special precautions for storage

Store in a refrigerator (2°C–8°C). The patient may store the product at temperatures below 25°C for 2 months whilst in use. The remaining ointment should then be discarded.

6.5 Nature and contents of container

Aluminium tube 20g.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Aspen Pharma Trading Limited,
3016 Lake Drive,
Citywest Business Campus,
Dublin 24,
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 39699/0087

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