SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Lidocaine 5% m/m Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine 5% m/m

For excipients. see 6.1.

3. PHARMACEUTICAL FORM

Ointment.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Local anaesthesia for topical use including, surface anaesthesia of gums in dentistry. Pain relief from anal fissures, pruritis ani, pruritis vulvae, haemorrhoids, herpes zoster and herpes labialis.

For symptomatic relief of sore nipples in nursing mothers.

As a lubricant in proctoscopy and cytoscopy.

4.2. Posology and Method of Administration

Cutaneous/oromucosal use.

Adult, elderly and children:

Dentistry: Apply to dry gum and rub gently.

Nursing mothers: Apply to the nipples using a small piece of gauze, wash off immediately before next feed.

All other indications: Apply 1 to 2 ml when required. Avoid long-term use which may lead to hypersensitivity.

4.3. Contra-Indications

Known sensitivity to lidocaine or other amide local anaesthetics.

4.4. Special Warnings and Special Precautions for Use

Lidocaine Ointment is not intended for use with aseptic techniques.

4.5. Interaction with other Medicinal Products and other Forms of Interaction

Although absorption of lidocaine from mucous membranes is marked, doses for topical anaesthesia are low. However, the following interactions should be considered:
Cimetidine and propranolol may inhibit the metabolism and thus enhance lidocaine toxicity.

4.6. Pregnancy and Lactation

In common with other drugs, Lidocaine Ointment should not be used in early pregnancy unless the benefits outweigh the potential risks.

4.7. Effects on Ability to Drive and Use Machines

No or negligible influence. Lidocaine administered parenterally may cause CNS stimulation, dizziness, nausea followed by depression and drowsiness.

4.8. Undesirable Effects

Allergic effects are uncommon to lidocaine but have been recorded, usually following parenteral administration. Hypersensitivity may occur in long-term topical use.

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

4.9. Overdose

Unlikely from topical use even if whole contents of a tube (750 mg lidocaine) has been ingested - oral bioavailability is low but hypotension and heart block may occur. Employ appropriate resuscitation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Anaesthetics Local. Amides. ATC code: NO1B B

Lidocaine is an amide local anaesthetic agent with a fast onset, blocking peripheral nervous conduction.

5.2 Pharmacokinetic Properties

a) *General characteristics:* Lidocaine is readily absorbed from mucosal surfaces, especially if inflamed. The plasma half-life is about 10 minutes following an intravenous dose, with an elimination half-life around 2 hours. Lidocaine will reach all tissues including transplacental transfer.

b) *Characteristics in patients:* Lidocaine undergoes first pass metabolism and is de-ethylated to monoethylglycylxylidide, glycylxylidide and 4-hydroxy-2,6-xylidine. These metabolites and unchanged lidocaine are excreted in the urine.

5.3 Pre-clinical Safety Data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Polyethylene Glycol 300
Polyethylene Glycol 4000

6.2 Incompatibilities

Not applicable.

6.3 Shelf-Life

Three years.

6.4 Special Precautions for Storage

Store below 25ºC.

6.5 Nature and Contents of Container

Internally lacquered aluminium tube fitted with a polythene cap. Pack size 15g.

6.6 Instructions for Use, Handling and Disposal

Apply using gauze or barrier gloves, if not available - wash hands after application.

7. MARKETING AUTHORISATION HOLDER

Teva UK Limited
Ridings Point,
Whistler Drive,
Castleford, WF10 5HX,
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

PL 00289/0761

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

17/09/1990 / 05/11/2002

10. DATE OF (PARTIAL) REVISION OF THE TEXT

21/02/2022