SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sore Mouth Gel or Boots Mouth Ulcer Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	Quantity
Lidocaine base	0.6 % w/w
Cetylpyridinium chloride	0.02 % w/w

Excipients of known effect	
ethanol (alcohol 96%)	35.00 % v/w
sucrose (refined sugar)	5 % w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oromucosal Gel

4.1 Therapeutic indications

For the rapid relief of pain caused by minor recurrent aphthous mouth ulcers and denture irritation.

4.2 Posology and method of administration

For topical application to the mouth and gums.

Adults and children aged 5 months and over

A small quantity of gel to be applied to the sore area with a clean finger and may be repeated after twenty minutes and then every three hours.

4.3 Contraindications

Hypersensitivity to the active ingredients or to any of the excipients listed in section 6.1)
Known hypersensitivity to local anaesthetics of the amide type
Current or past history of methaemoglobinaemia.
Babies under 5 months

4.4 Special warnings and precautions for use

To be used with caution in patients with hepatic or cardiac dysfunction.
Do not exceed the stated dose. Not recommended for infants under five months.

Keep all medicines out of the reach of children.
If symptoms persist consult your doctor or dentist.
Not suitable for treatment of teething in children.
Excessive dosage, short intervals between doses or use on traumatised mucosa may result in high plasma levels and serious adverse effects (see Section 4.9).

This medicine contains 350 mg of alcohol (ethanol) in each 1g of gel. The amount in 0.2g of this medicine is equivalent to less than 1.6 ml beer or 1.1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interaction

Concurrent use of either cimetidine or propranolol increases the risk of lidocaine toxicity. Lidocaine is antagonised by those diuretics which cause hypokalaemia.

Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics, e.g. antiarrhythmic drugs such as mexiletine, since the toxic effects may be additive.

In patients taking erythromycin the toxicity of oral lidocaine may be increased.

In patients taking itraconazole, the toxicity of oral lidocaine may be increased.

4.6 Fertility, pregnancy and lactation

Pregnancy:
The safety of this product during pregnancy has not been established. The product is, therefore, not recommended during pregnancy and lactation except under medical supervision.

Lactation/Breastfeeding:
Lidocaine enters breast milk, but in such small quantities there is generally no risk of the child being affected at therapeutic dose levels.
No adverse effects have been seen in breastfed infants whose mothers were receiving lidocaine and it is therefore usually compatible with breast feeding.

Fertility:
No data on human fertility are available.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Adverse reactions have been ranked under headings of frequency using the following 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
Not known: Frequency unable to be classified from available data.
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ Class	Preferred Term	Frequency
Blood and lymphatic system disorders	Methaemoglobinaemia	Not known
Immune System Disorders	Hypersensitivity	Not known
Skin and subcutaneous tissue disorders	Contact dermatitis	Not known

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 by searching for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

Overdose is highly unlikely given the size of the pack. No experience of overdosage.
It is most unlikely, even with misuse or excessive application of the gel, that the large amounts of lidocaine hydrochloride or cetylpyridinium chloride required to produce clinically-relevant toxic effects would be reached. In the event of overdose, use should be discontinued and a doctor consulted.

The toxic effects of lidocaine are directly related to blood concentrations.
Symptoms

are dizziness, cyanosis due to methaemoglobinaemia, muscular tremors, convulsions,
coma, irregular and weak breathing, cardiac standstill, bronchial spasm, severe hypotension, asystole, bradycardia, apnoea, seizures, coma, cardiac arrest, respiratory arrest, and death.

Management
In the unlikely event of overdose with this product, immediate treatment should be
sought which should be symptomatic and supportive.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Lidocaine, combinations; ATC Code: N01BB52

Lidocaine is a local anaesthetic of the amide type, acting to produce reversible loss of sensation by preventing or diminishing the generation and transmission of sensory
nerve impulses near the site of application. Depolarisation of the neuronal membrane
and ion exchange are reversibly inhibited.

Cetylpyridinium chloride is a quaternary pyridinium antiseptic with actions and uses
similar to those of other cationic surfactants.

5.2 Pharmacokinetic properties

Lidocaine is rapidly absorbed from mucous membranes. The plasma elimination half life is about two hours.

Lidocaine undergoes significant first pass metabolism in the liver and is rapidly de-ethylated to the active metabolite monoethyiglycinexylidide and then hydrolysed to various metabolites including glycinexylidide. Less than 10% is excreted unchanged by the kidneys. The metabolites are also excreted in the urine.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Refined sugar

Cetomacrogol 1000

Hypromellose

Alcohol 96%

Eucalyptol

Levomenthol synthetic or natural

Star Anise oil

Purified water

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

A collapsible aluminium tube, internally lacquered with a polyamide/polyimide lacquer system with a membrane seal fitted with a wadless polythene cap or polyporpylene cap.

Pack size: 15 gm.

6.6 Special precautions for disposal

None stated.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC

1 Thane Road West

Nottingham NG2 3AA

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0150

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25/06/1974 / 16/04/2002

10 DATE OF REVISION OF THE TEXT

10/06/2024