1 NAME OF THE MEDICINAL PRODUCT

Savlon Bites & Stings Pain Relief Gel

Savlon Antiseptic and Pain Relief Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:	Lidocaine Hydrochloride	2.0% w/w
	Zinc Sulphate	1.0% w/w
	Cetrimide	0.5% w/w

Excipient(s) with known effect:

Propylene glycol (E1520)	10.0% w/w

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gel

Colourless, viscous gel with a characteristic menthol odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of pain, itching, irritation, and for antiseptic protection. For use in insect bites and stings, and skin reactions such as nettle rash, caused by contact with plants.

4.2 Posology and method of administration

Adults and children over 12 years: Apply a small amount to the affected area with a fingertip. Repeat if required up to 3-4 times daily.

Children under 12 years: Not recommended (insufficient data available).

Route of administration: For cutaneous use.

4.3 Contraindications

Patients with a known hypersensitivity to any ingredient should not use the product.

4.4 Special warnings and precautions for use

Contact with the eyes should be avoided. For external use only.

Not suitable for animal bites.

Keep out of the sight and reach of children.

Excipient warnings:

This medicine contains 10%w/w propylene glycol (E1520) per application, which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No known interactions with other drugs.

4.6 Fertility, Pregnancy and lactation

There are no known adverse effects in normal use of this product in pregnancy and lactation.

Exposure to systemically absorbed lidocaine from the product is low. The active ingredients have been in use for many years and no special precautions are considered necessary.

4.7 Effects on ability to drive and use machines

There are no known adverse effects on driving and using machinery.

The active ingredients have been in use for many years at much higher levels of exposure and no precautions are considered necessary for use in driving and using machinery.

4.8 Undesirable effects

Rarely, skin irritation and sensitisation may occur.

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.

4.9 Overdose

Overdosage effects are unlikely as the systemic dose from this topical product is likely to be very low.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Three pharmacological effects are provided:

Lidocaine hydrochloride is a local anaesthetic of the amide type which is widely used for local application to the skin and mucous membranes. It produces surface anaesthesia by diminishing or preventing the conduction of sensory nerve impulses.

Cetrimide is a quaternary ammonium antiseptic. As well as having emulsifying and detergent properties, it has antibacterial activity against gram-positive organisms and to a lesser extent against some gram-negative organisms.

Zinc sulphate has astringent and soothing properties.

5.2 Pharmacokinetic properties

The product is intended for local action. Lidocaine hydrochloride is well-absorbed through mucous membranes and more slowly absorbed through intact skin.

5.3 Preclinical safety data

No relevant information is available other than that given in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hypromellose

Polysorbate 20

Nonoxinol 9

Propylene Glycol (E1520)

Levomenthol

Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

Shelf life after opening of the tube: 3 months

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Laminated tube consisting of aluminium foil coated internally and externally with low density polyethylene or high density polyethylene.

Pack size: 3g, 20g

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.

Linthwaite,

Huddersfield,

HD7 5QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0468

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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