SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pinewood's Bites and Stings Relief Cream
Sainsbury's Healthcare Bites and Stings Relief 1% w/w Cream
Morrison's Bites and Stings Relief 1% w/w Cream
Numark Bites and Stings Relief 1% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone 1% w/w
For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cream
Hydrocortisone 1% Cream is a smooth white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hydrocortisone has topical anti-inflammatory activity of value in the treatment of insect bite and sting reactions.

4.2 Posology and method of administration

For cutaneous use.

Adults and Children aged 10 years and over:
Use sparingly over a small area once or twice a day for a maximum period of 2-3 days. If the condition has not improved, or worsens, consult your doctor. This product should not be recommended for use on children under 10 years of age without medical supervision.

4.3 Contraindications

Bacterial (e.g. impetigo), viral (e.g. Herpes simplex) or fungal (e.g. candidal or dermatophyte) infections of the skin.
Hypersensitivity to any of the ingredients.
Use on the eyes and face, ano-genital region, broken or infected skin including cold sores, acne and athletes foot.

4.4 Special warnings and precautions for use

The label will state:
Contains hydrocortisone. Do not use on the eyes, face or ano-genital region, broken or infected skin including scabies and infected bites and strings.

Do not use in pregnancy without medical advice.
Do not use on children under 10.
Stop treatment if symptoms of hypersensitivity occur.
If the condition does not improve after 2-3 days consult a doctor.
Not to be used for other bites or stings or for other skin conditions.

Chlorocresol may cause allergic reactions.
Cetomacrogol emulsifying wax contains cetostearyl alcohol which may cause local skin reaction (e.g. contact dermatitis)

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

This product should not be used in pregnancy without medical advice. There is no information about effects on lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Hydrocortisone preparations are usually well tolerated, but if any signs of hypersensitivity appear, application should be stopped immediately.

Striae may occur especially in intertriginous areas.

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

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D07A A02. Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction on the vascular component of the inflammatory response and reduction in the formation of inflammatory fluid and cellular exudates. The granulation reaction is also decreased due to the inhibition effect of Hydrocortisone on connective tissue. Stabilisation of most cell graduates and lysomal membranes decreases the mediators involved in inflammatory response and reduces release of enzymes in prostaglandin synthesis. The vasoconstrictor action of Hydrocortisone may also contribute to its anti-inflammatory activity.

5.2 Pharmacokinetic properties

Absorption: Topically applied steroids are absorbed to a significant extent only if applied to broken skin, to very large areas, or under occlusive dressings.
Distribution: Corticosteroids are rapidly distributed to all body tissues. They cross the placenta and may be excreted in small amounts in breast milk.
Metabolism: Hydrocortisone is metabolized mainly in the liver but also the kidney, to various degraded and hydrogenated forms such as tetrahydrocortisone.
Elimination: Hydrocortisone is excreted in the urine, mostly conjugated glucuronides. Only very small amounts of unchanged hydrocortisone are excreted.

5.3 Preclinical safety data

Adverse effects of Hydrocortisone are due to its effect on electrolyte balance, metabolism and particularly adrenal suppression. Topical use of Hydrocortisone has only rarely been associated with systemic side effects.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetomacrogol Emulsifying Wax
Chlorocresol
Liquid Paraffin
Macrogol 300
White Soft Paraffin
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

A collapsible aluminum tube, with a membrane seal at the nozzle, internal epoxy lacquer, latex end seal band in the crimp seal and a white plastic cap for reclosure after piercing membrane.
Pack Size: 10g.

6.6 Special precautions for disposal

No special precautions required.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Limited
Trading as Pinewood Healthcare
Ballymacarbry
Clonmel
Co Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 04917/0062

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/11/2008

10 DATE OF REVISION OF THE TEXT

14/12/2015