SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Skincalm Bite and Sting Relief 1% Cream
Hydrocortisone

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cream containing 1% micronised hydrocortisone

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Cream

White Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Insect bite and sting reactions only

4.2 Posology and method of administration

For cutaneous use.

Adults and elderly: Apply sparingly to a small area once or twice daily for a maximum period of 2-3 days. If the condition does not improve consult your doctor.

Children aged 10 years and above: as for adults and the elderly. Do not use for children under 10 years old.

4.3 Contraindications

- Hypersensitivity to any of the ingredients.
- Use on the eyes, face or ano-genital region.
- Use on broken or infected skin, including acne, infected bites and stings, skin lesions caused by infections with viruses (e.g. herpes infections such as cold sores, chicken pox, scabies and infected bites and stings), fungi (e.g. athlete's foot and, ringworm) or bacteria (e.g. impetigo).
- Children under 10 years of age.
- Not to be used for other bites and stings or other skin conditions.

4.4 Special warnings and precautions for use

This medicine contains chlorocresol which may cause allergic reactions.

The product labelling will convey the following information:
For application to the skin only.

Do not use on the eyes or face, anal or genital areas or on broken or infected skin e.g. acne, impetigo, cold sores, athletes foot, scabies, infected bites or stings. Do not use for other bites and stings or for other skin conditions.

Do not use if you are allergic to any of the ingredients. Do not use during pregnancy without medical advice.

This product should not be used on children under the age of 10 years.

If the condition does not improve consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-growth retardation. There may therefore be a very small risk of such effects in the human foetus.

The product should not be used in pregnancy without medical advice.

There is no evidence against use in lactating women. However, caution should be exercised when hydrocortisone cream is administered to nursing mothers. In this event, the product should not be applied to the chest area.

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 including allergic contact dermatitis or worsening of the original condition appear, treatment should be stopped immediately.

Epidermal thinning, telangiectasia and striae may occur in areas of high absorption such as skin folds. Skin pigmentation changes and hypertrichosis may occur after application of topical steroids.

4.9 Overdose

Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse the features or hypercorticism may appear and in this situation topical steroids should be discontinued.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction of the vascular component of the inflammatory response and reduction of 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 granules and lysomal membranes decreases the mediators involved in inflammatory response and reduces release of enzymes involved 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 metabolised 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 as glucuronides. Only very small amounts of unchanged hydrocortisone are excreted.

5.3 Preclinical safety data

Adverse effects of hydrocortisone are due to its effects 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 25ºC

6.5 Nature and contents of container

A collapsible aluminium tube, with a membrane seal at the nozzle, internal epoxy lacquer, latex endseal band in the crimp seal area and a white plastic cap for re closure after piercing membrane.

10g pack size only.

6.6 Special precautions for disposal

No special precautions are required

7. MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 13606/0181

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/09/2011

10 DATE OF REVISION OF THE TEXT

27/04/2017