# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Hydrocortisone Cream 1%
Skin Calm Cream

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cream containing 1% micronised hydrocortisone.

For excipients, see 61.

## 3. PHARMACEUTICAL FORM

Cream

White Cream.

## 4 CLINICAL PARTICULARS

### 4.1. Therapeutic Indications

Hydrocortisone has topical anti-inflammatory activity of value in the treatment of irritant dermatitis, contact allergic dermatitis, insect bite reactions and mild to moderate eczema.

### 4.2 Posology and method of administration

Use sparingly over a small area once/twice a day for a maximum period of one week.
Wash hands after application unless these are the intended site of treatment.
If the condition is not improved, consult your doctor.

### 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 skin lesions caused by infections with viruses (e.g. herpes infections such as cold sores, chicken pox), fungi (e.g. athlete's foot, ringworm, thrush) or bacteria (e.g. impetigo)
- Acne

The product is not recommended for use on children under 10 years of age without medical supervision.

## 4.4 Special warnings and precautions for use

This product should not be used under an occlusive dressing or napkin because of the potential for increased absorption of hydrocortisone and subsequent risk of adrenal suppression.

In infants and children, long-term contiuous topical therapy with hydrocortisone should be avoided where possible, as adrenal suppression can occur even without occlusion. Treatment should be limited to a maximum of 7 days.

Care should be taken to avoid transfer of product to the eye or periorbital region. Increased intraocular pressure or glaucoma has been reported following use of topical steroids around the eye.

## 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.

There is no evidence against use in lactating women. However, caution should be exercised when hydrocortisone ointment 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.

Although less likely than with other more potent topical corticosteroids, prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce suppression of the hypothalamic-pituitary-adrenal axis and the clinical features of Cushing's syndrome (see section 4.4). These effects are more likely to occur in infants and children, and if occlusive dressings are used. In infants the napkin may act as an occlusive dressing.

Striae may occur in intertriginous areas.

### 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 execreted.

### 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 25°C.

### 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 reclosure after piercing membrane.

Pack sizes are 10 and 15 g. Not all pack sizes are marketed.

### 6.6. Instructions for Use/Handling

No special precautions are required.

## 7. MARKETING AUTHORISATION HOLDER

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## 8. MARKETING AUTHORISATION NUMBERS

PL 13606/0022

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

9th October 1996

## 10 DATE OF REVISION OF THE TEXT

27/04/2017