SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hydrocortisone 1% w/w Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 gram of the ointment contains 10 mg of Hydrocortisone (i.e. 1 %w/w).

Excipient with known effect
Each 1 gram of the ointment contains 100 mg (10 %w/w) of wool fat.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A smooth uniform, yellowish white, translucent ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Hydrocortisone has topical anti-inflammatory activity of value in the treatment of a wide variety of dermatological conditions, including the following: eczema and dermatitis of all types including atopic eczema, photodermatitis, intertrigo, primary irritant and allergic dermatitis, prurigo nodularis, seborrhoeic dermatitis and insect bite reactions.

4.2 Posology and method of administration

Posology
Apply, once to four times daily gradually increasing the intervals between applications as the condition improves. Treatment may then be reduced to two to three times a week or when symptoms recur. Gentle massage assists penetration.

Method of administration
For cutaneous use

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 the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Remarks on indications

1. There is no good evidence that topical corticosteroids are efficacious against immediate (Type 1) allergic skin reactions or short-lived weal and flare reactions from other causes.

2. Topical corticosteroids are ineffective in granulomatous conditions and other inflammatory reactions involving the deeper regions of the dermis.

3. Topical corticosteroids are not generally indicated in psoriasis excluding widespread plaque psoriasis provided that warnings are given.

Topical corticosteroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of generalised pustular psoriasis, and local and systematic toxicity due to impaired barrier function of the skin. Careful patient supervision is important.

Although generally regarded as safe, even for long-term administration in adults, there is potential for overdosage in infants and children. Extreme caution is required in dermatoses of infancy especially napkin eruption where the napkin can act as an occlusive dressing and increase absorption. In infants and children, courses of treatment should therefore not normally exceed 7 days.

Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions, which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy, and a systemic administration of antimicrobial agents.

As with all corticosteroids, prolonged application to the face is undesirable.

This medicinal product contains wool fat (lanolin), which may cause local skin reactions (e.g. contact dermatitis).

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Topical steroid withdrawal syndrome :

Long term use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

The label will state mild steroid.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy
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-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

Breastfeeding
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 appear, application should stop immediately.

Striae may occur especially in intertriginous areas.

Skin and Subcutaneous Tissue Disorders: Not known (cannot be estimated from available data)
Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

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

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, mild (group 1); ATC code: D07A A02

Hydrocortisone is an anti-inflammatory steroid. Its anti-inflammatory action is due to reduction in 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 granules 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 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 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

Wool Fat
Liquid Paraffin
White Soft Paraffin

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 end seal band in the crimp seal and a white plastic cap for reclosure after piercing membrane.

Pack Sizes: 5g, 10g, 15g, 20g, 30g and 50g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

PL 04917/0145

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/02/2025

10 DATE OF REVISION OF THE TEXT

19/02/2025