SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Hydrocortisone Ointment

Boots Derma Care Hydrocortisone 1% Ointment

Almus Hydrocortisone 1% Ointment

Boots Derma Care 1% w/w Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	%w/w
Hydrocortisone Ph Eur	1.0

3. PHARMACEUTICAL FORM

Ointment

4.1 Therapeutic indications

For the relief of irritant contact dermatitis, allergic contact dermatitis, insect bite reactions and mild to moderate eczema.

4.2 Posology and method of administration

Posology
For adults, the elderly and children over 10 years of age: Apply once or twice a day, for a maximum of 7 days. If the condition is not improved, consult your doctor.

Dosage recommendations as above for children over 10 years of age. The product should not be used in children under 10 years of age without medical advice.

Method of administration
For topical application.

Apply accurately and sparingly to a small area. Massage gently into the skin.

4.3 Contraindications

Hypersensitivity to hydrocortisone or to any of the excipients listed in section 6.1.

The product should not be used on the eyes or face (for example, in rosacea or perioral dermatoses), the ano-genital area or on broken or infected skin including impetigo, cold sores, acne, athlete's foot, or infected bites and stings.

In the presence of untreated infections of bacterial, viral, tuberculous or fungal origin.

Not for use with an occlusive dressing or on large areas of the body.

4.4 Special warnings and precautions for use

The label will state ‘mild steroid’.

The product should not be used during pregnancy or breast-feeding unless recommended by a health care professional (see section 4.6).

If the condition does not improve consult your doctor. Prolonged use of the product is not recommended (see section 4.2) as continuous uninterrupted application may cause local atrophy of the skin, striae and superficial vascular dilatation.

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 advice is recommended in these cases or other treatment options should be considered.

Visual impairment:
Visual impairment may be reported with systemic and topical use of corticosteroids. If patients develop symptoms such as blurred vision or other visual disturbances, consideration should be given to referring the patient to an ophthalmologist to establish the possible cause which may include cataract, glaucoma or rare conditions such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interactions with other medicaments and other forms of interaction

No clinically significant interactions known.

4.6 Fertility, pregnancy and lactation

Pregnancy
This product should not be used in pregnancy without medical advice. There are no or limited amount of data from the use of topical corticosteroids in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

Breast-feeding
This product should not be used whilst breast-feeding unless recommended by a health care professional. Corticosteroids are excreted in human milk. There is no information about effects on lactation. A risk to new-borns/infants cannot be excluded.

Fertility
No known effects.

4.7 Effects on ability to drive and to use machines

No adverse effects known.

4.8 Undesirable effects

If any signs of hypersensitivity, including allergic contact dermatitis or worsening of the original condition appear, treatment should be immediately discontinued.

Adverse events which have been associated with topical corticosteroids are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Skin and subcutaneous tissue disorders	Not known	Skin atrophy, telangiectasia, skin striae, acne, rosacea, pigmentation disorder, hypertrichosis. 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).
Musculoskeletal and connective tissue disorders	Not known	Collagen disorder.
Eye disorders	Uncommon	Vision blurred (see also 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

Acute overdose is highly unlikely. No special precautions or antidotes are likely to be needed. Chronic overdose or misuse may increase the risk of topical or systemic steroid-related adverse effects, including hypothalamic pituitary adrenal (HPA) axis

suppression and Cushing's syndrome.

Management of overdose with topical corticosteroids includes gradual discontinuation under medical supervision.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, weak (group I), ATC code: D07AA02

Hydrocortisone is a corticosteroid which has anti-inflammatory activity resulting, at least in part, from binding with a steroid receptor. Hydrocortisone acetate reduces inflammation by stabilising cell membranes, preventing the release of destructive enzymes, antagonising histamine and the release of kinins, inhibiting accumulation of macrophages and reducing capillary wall permeability and oedema formation.

This medicine is classed as a mild corticosteroid.

5.2. Pharmacokinetic Properties

Following topical application to most areas of normal skin, only minimal amounts of the drug reach the dermis and subsequently the systemic circulation. Absorption may be markedly increased when the skin has lost its keratin layer and can be increased by inflammation or diseases of the epidermal barrier. Hydrocortisone is absorbed to a greater degree from the scrotum, axilla, eyelid, face and scalp than from the forearm, knee, elbow, palm and sole.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

Whilst there is inadequate evidence on safety in human pregnancy, animal studies have demonstrated a possible association between topical corticosteroids and foetal abnormalities, including cleft palate and intra-uterine growth retardation.

6.1. List of Excipients

White soft paraffin.

6.2. Incompatibilities

Not applicable.

6.3. Shelf Life

36 months.

6.4. Special Precautions for Storage

Do not store above 25°C.

6.5 Nature and contents of container

15 gram internally lacquered, collapsible, aluminium tubes with polypropylene caps. The tubes are packed into cartons.

6.6 Special precautions for disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham NG2 3AA

Trading as: BCM

8. MARKETING AUTHORISATION NUMBER(S)

PL 00014/0364.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14 April 1987 / 17 June 1997

10 DATE OF REVISION OF THE TEXT

15/07/2024