Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

HC45 Hydrocortisone Acetate Cream (Hydrocortisone Acetate 1% w/w)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone acetate 1% w/w.

Excipients:
Cetostearyl alcohol 7.2% w/w

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
White, odourless or almost odourless cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Allergic contact dermatitis
Irritant contact dermatitis
Insect bite reactions
Mild to moderate eczema

4.2 Posology and method of administration

Adults and children over 10 years: Once or twice a day, for a maximum of 7 days.

Medical advice should be sought if the condition does not improve.

Elderly population
Dosage adjustments are not considered necessary in the elderly.

Paediatric population
Dosage recommendations as above for children over 10 years of age. The product should not be used in children under 10 years of age unless recommended by a health care professional.

Method of administration
For topical administration.
Apply sparingly to a small area. Massage gently into the skin.

4.3 Contraindications

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

Do not use 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 or athlete's foot or infected bites or stings).

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

Prolonged use of the product is not recommended (see section 4.2) as continuous application without interruption will result in local atrophy of the skin, striae and superficial vascular dilatation, particularly of the face.

Long term continuous or inappropriate 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.

Prolonged use of uninterrupted occlusion or use with extensive occlusive dressings may suppress adrenocortical function.

This product contains ceteostearly alcohol which may cause local skin reactions (e.g. contact dermatitis).

Visual disturbance:
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Should not be used in pregnancy unless considered essential by the physician. There are no or limited amount of data from the use of topical corticosteroids in pregnant women. Studies in animals have shown reproductive toxicity.

Breast-feeding

The product should not be used whilst breast-feeding unless recommended by a health care professional. Corticosteroids are excreted in human milk. A risk to new-borns/infants cannot be excluded.

Fertility

No known effects.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

As hydrocortisone acetate is a weak corticosteroid, topical preparations are usually well tolerated, especially under recommended use, where treatment exposure and duration is restricted (see section 4.2).

Undesirable effects from topical corticosteroids are more commonly associated with potent corticosteroids compared with weak agents like hydrocortisone acetate. Adverse effects are very uncommon and typically linked with prolonged therapy or

misuse (see section 4.9). 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 ofthe skin which may extend to areas beyond the initial affected area, burning orstinging 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No special antidotes are likely to be required.

Acute overdose is highly unlikely. 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, dermatological preparations; corticosteroids, weak (group I); **ATC Code:** D07AA02

Hydrocortisone is a corticosteroid which has anti-inflammatory activity.

5.2 Pharmacokinetic properties

Hydrocortisone acetate is a well characterised 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.

5.3 Preclinical safety data

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.

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 layers and can be increased by inflammation or diseases of the epidermal barrier.

Hydrocortisone is absorbed to a greater degree from scrotum, axilla, eyelid, face and scalp than from the forearm, knee, palm and sole.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin
Liquid paraffin
Cetomacrogol emulsifying wax (includes cetostearyl alcohol)
Phenoxyethanol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Internally lacquered, membrane-sealed, collapsible aluminium tube with polypropylene or high density polythene cap containing 15g cream.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

KARO PHARMA AB
Box 16184
103 24 Stockholm
Sweden

8 MARKETING AUTHORISATION NUMBER

PA22650/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 September 1996

Date of last renewal: 24 September 2006

10 DATE OF REVISION OF THE TEXT

September 2022