# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. Name of the medicinal product

**ESTROCORTISONE CREAM (**Hydrocortisone Acetate USP 1.0% Cream)

## 2. Qualitative and quantitative composition

Composition:
Hydrocortisone Acetate USP 1.0 % w/w
In a Cream Base q.s

## 3. Pharmaceutical form

Topical Cream
A smooth white to off white cream

## 4. Clinical particulars

### 4.1 Therapeutic indications

**ESTROCORTISONE CREAM (**Hydrocortisone Acetate USP 1.0% Cream) is indicated for the treatment of eczema and dermatitis of all types, including atopic eczema, photodermatitis, otitis externa, primary irritant and allergic dermatitis, intertrigo, prurigo nodularis, seborrhoeic dermatitis and insect bite reactions.

### 4.2 Posology and method of administration

For topical administration.
*Adults and children:* To be applied sparingly to the affected skin two or three times daily after gently cleansing the area. Courses of treatment in children should generally be limited to not more than seven to ten days.

### 4.3 Contraindications

Hydrocortisone Cream is contra-indicated in patients with bacterial, viral or fungal infections of the skin. Urticaria, rosacea, ulcers and local infection are also contra-indications.

### 4.4 Special warnings and precautions for use

Prolonged use in infants and children and on the face should be avoided.

Hydrocortisone Cream is for symptomatic relief and is not curative. For this reason, there is a possibility of rebound of symptoms.
Hydrocortisone Cream is not recommended for pruritis.

Topical corticosteroids may be hazardous in patients with psoriasis and should therefore be avoided.

Long term use in patients with diabetes or tuberculosis is not recommended.

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.

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

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

No known interactions.

## 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-uterine growth retardation. Thus, there may be a very small risk of such effects in the human foetus.

No problems have been documented for neonates when Hydrocortisone Cream is used by nursing mothers.

## 4.7 Effects on ability to drive and use machines

No adverse effects known.

## 4.8 Undesirable effects

Side effects are rare but the following local effects have been reported frequently:

Spread of infection, irreversible striae atrophicae, thinning of the skin, changes in hair growth, acne, oily skin and mild depigmentation.

Serious systemic effects of pituitary suppression and hypercorticism may occur if significant systemic absorption occurs. This is likely if applied frequently or over prolonged periods or over a large areas or over moist and /or denuded areas or if an occlusive dressing is present. Systemic absorption is more likely when used over intertriginous areas. Children are particularly at risk and in these patients, Hydrocortisone Cream should only be used twice daily for a maximum of ten days over a body surface area not exceeding 10% and without an occlusive dressing.

Vision, blurred (see also section 4.4) (uncommon)

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

Following oral ingestion, symptoms may include nausea, vomiting and diarrhoea.

Treatment need only be symptomatic.

No special procedures or antidotes are likely to be needed.

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

Hydrocortisone is a corticosteroid which has anti-inflammatory activity.

### 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, eyelids, face and scalp than from the forearm, knee, elbow, palm and sole.

### 5.3 Preclinical safety data

Not applicable.

## 6. Pharmaceutical particulars

### 6.1 List of excipients

| Sr.No. | Raw Material | Pharmacopoeia |
|---|---|---|
| 1. | Cetostearyl Alcohol | BP |
| 2. | Cetomacrogol 1000 | IHS |
| 3. | White Soft Paraffin | BP |
| 4. | Light Liquid Paraffin | BP |

| | | |
|---|---|---|
| 5. | Propylene Glycol | BP |
| 6. | Disodium Edetate | BP |
| 7. | Disodium Hydrogen Phosphate Dihydrate | BP |
| 8. | Sodium Dihydrogen Phosphate Dihydrate | BP |
| 9. | Butylated Hydroxyanisole | BP |
| 10. | Butylated Hydroxytoluene | BP |
| 11. | Methyl Hydroxybenzoate | BP |
| 12. | Propyl Hydroxybenzoate | BP |
| 13. | Chlorocresol | BP |
| 14. | Purified Water | BP |

**6.2 Incompatibilities**

No major incompatibilities known.

**6.3 Shelf life**

36 months.

**6.4 Special precautions for storage**

Store below 30ºC in dry and dark place. Do not freeze.

**6.5 Nature and contents of container**

15 g cream filled in an aluminium tube packed in a carton.

**6.6 Special precautions for disposal and other handling**

None.

**7. Marketing authorisation holder**

**Kilitch Drugs (India) Limited**
**37, Ujagar Industrial Estate,**
**W.T Patil Marg, Deonar,**
**Mumbai 400 088,Maharashtra, India.**
**Website- www.kilitch.com**

**8. Marketing authorisation number(s) issued by Ethiopian FDA**

07840/08807/NMR/2021

**9. Date of first authorisation/renewal of the authorisation**

30-09-2022

**10. Date of revision of the text**

06/07/2023