

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1. Name of the medicinal product**

BEEGEE CREAM (Betamethasone Dipropionate Cream USP)

## **2. Qualitative and quantitative composition**

- Betamethasone Dipropionate USP  
eq. to Betamethasone..... (0.05 % W/W)
- Cream Base..... (Q.S.)

For the full list of excipients see section 6.1

## **3. Pharmaceutical form**

Cream

## **4. Clinical particulars**

### **Therapeutic indications**

Betamethasone Dipropionate is a synthetic fluorinated corticosteroid. It is active topically and produces a rapid and sustained response in eczema and dermatitis of all types, including atopic eczema, photodermatitis., lichen planus, lichen simplex, prurigo nodularis, discoid lupus erythematosus, necrobiosis lipoidica, pretibial myxedema and erythroderma. It is also effective in less responsive conditions such as psoriasis of the scalp and chronic plaque psoriasis of the hands and feet but excluding widespread plaque psoriasis.

### **Posology and method of administration**

#### **Adults and Children:**

Once to twice daily. In most cases a thin film of Beegee Cream should be applied to cover the affected area twice daily. For some patient's adequate maintenance therapy may be achieved with less frequent application.

Beegee Cream is especially appropriate for moist or weeping surfaces and the ointment for dry, lichenified or scaly lesions but this is not invariably so.

#### **Contraindications**

Rosacea, acne, perioral dermatitis, perianal and genital pruritus. Hypersensitivity to any of the ingredients of the Beegee Cream presentations contra-indicates their use as does tuberculous and most viral lesions of the skin, particularly herpes simplex, vaccinia, varicella. Beegee Cream should not be used in napkin eruptions, fungal or bacterial skin infections without suitable concomitant anti-infective therapy.

### **Special warnings and precautions for use**

Local and systemic toxicity is common, especially following long continuous use on large areas of damaged skin, in flexures or with polythene occlusion. If used in children or on the face courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

Occlusion must not be used.

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

**General:** Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome also can be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients receiving a large dose of a potent topical steroid applied to a large surface area should be evaluated periodically for evidence of HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid.

Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Any of the side effects that are reported following systemic use of corticosteroids, including adrenal suppression, may also occur with topical corticosteroids, especially in infants and children.

Paediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, treatment should be discontinued, and appropriate therapy instituted.

Beegee Cream is not for ophthalmic use.

#### **Paediatric Use:**

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and to exogenous corticosteroid-induced HPA axis suppression and to exogenous corticosteroid effects than adult patients because of greater absorption due to a larger skin surface area to body weight ratio. HPA axis suppression, Cushing's syndrome and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in paediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include a bulging fontanelle, headaches and bilateral papilledema.

### **Interaction with other medicinal products and other forms of interaction**

None stated.

### **Fertility, pregnancy and lactation**

There are no adequate and well controlled studies of the teratogenic potential of topically applied corticosteroids in pregnant women. Therefore, topical steroids should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

It is not known whether topical administration of corticosteroids would result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

### **Effects on ability to drive and use machines**

None stated.

### **Undesirable effects**

Beegee Cream skin preparations are generally well tolerated and side-effects are rare. The systemic absorption of betamethasone dipropionate may be increased if extensive body surface areas or skin folds are treated for prolonged periods or with excessive amounts of steroids. Suitable precautions should be taken in these circumstances, particularly with infants and children.

The following local adverse reactions that have been reported with the use of Beegee Cream include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, striae and miliaria.

Continuous application without interruption may result in local atrophy of the skin, striae and superficial vascular dilation, particularly on the face.

### **Overdose**

Excessive prolonged use of topical corticosteroids can suppress pituitary-adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. In such cases appropriate symptomatic treatment is indicated. If HPA axis suppression is noted, an attempt should be made to withdraw the drug, reduce the frequency of application, or to substitute a less potent steroid.

The steroid content of each tube is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.

## **5. Pharmacological properties**

### **Pharmacodynamic properties**

Beegee Cream preparations contain the dipropionate ester of betamethasone which is a glucocorticoid exhibiting the general properties of corticosteroids.

In pharmacological doses, corticosteroids are used primarily for their anti-inflammatory and/or immune suppressive effects.

Topical corticosteroids such as betamethasone dipropionate are effective in the treatment of a range of dermatoses because of their anti-inflammatory, anti-pruritic and vasoconstrictive actions. However, while the physiologic, pharmacologic and clinical effects of the corticosteroids are well known, the exact mechanisms of their action in each disease are uncertain.

### **Pharmacokinetic properties**

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of the epidermal barrier and the use of occlusive dressings. Topical corticosteroids can be absorbed through intact, normal skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids.

Once absorbed through the skin, topical corticosteroids enter pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees, are metabolised primarily in the liver and excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

### **Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## **6. Pharmaceutical particulars**

### **List of excipients**

Cetomacrogol 1000 INH

Cetostearyl Alcohol BP

White Soft Paraffin BP

Sodium Acid Phosphate BP

Disodium Hydrogen Phosphate BP

Benzyl alcohol BP

Liquid Paraffin (Heavy) BP

Propylene Glycol BP

Purified Water BP

### **Incompatibilities**

None known.

**Shelf life**

36 months

**Special precautions for storage**

Store at a temperature not exceeding 30°C.

**Nature and contents of container**

30 gm lami tube packed in inner carton along with the leaflet.

**Special precautions for disposal and other handling**

Not applicable.

**7. Marketing authorisation holder**

**KREMOINT PHARMA PVT. LTD.**

Plant: B-8, Additional Ambernath,

M.I.D.C., Ambernath (East),

Dist. Thane – 421 506.

**8. Marketing authorisation number(s)**

Registration Number: 04957/06690/NMR/2018

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

Approval Date: 04.02.2020

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

Revision of Text : 04.02.2025