SUMMARY OF PRODUCT CHARACTERISTICS

1. **Name of the medicinal product**

1.1 (Invented) name of the medicinal product:

- **Generic Name/Inn Name:**
  Betamethasone Dipropionate Cream USP

- **Brand Name:**
  Sicacort-BD Cream

1.2 Strength :
Betamethasone Dipropionate USP Eq. to Betamethasone USP 0.05% w/w

1.3 Pharmaceutical form :
Topical cream

2. Qualitative and quantitative composition:

Sr. No.	Ingredients	Specification	Standard Quantity (%w/w)	Standard Quantity (kg/batch)	Functions
1	Betamethasone Dipropionate USP eq.Betamethasone USP	USP	0.05 %	0.321	Active

3. Pharmaceutical form:

- **Dosage Form:** Topical cream
- **Visual & Physical characteristics of the product:** White coloured soft cream

4. Clinical particulars:

4.1 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 myxodemea and erythroderma. It is also effective in the less responsive conditions such as psoriasis of the scalp and chronic plaque psoriasis of the hands and feet, but excluding widespread plaque psoriasis.

4.2 Posology and method of administration:

Adults and Children:

Once to twice daily. In most cases a thin film of Sicacort-BD Cream should be applied to cover the affected area twice daily. For some patients adequate maintenance therapy may be achieved with less frequent application.

Sicacort-BD Cream is specially appropriate for moist or weeping surfaces and the ointment for dry, lichenified or scaly lesions but this is not invariably so.

Control over the dosage regimen may be achieved during intermittent and maintenance therapy by using Diprobase Cream or Ointment, the base vehicles of Sicacort-BD Cream and Ointment. Such control may be necessary in mild and improving dry skin conditions requiring low dose steroid treatment.

4.3 Contraindications:

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

4.4 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 generalised 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. If 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.
Sicacort-BD is not for ophthalmic use. Visual disturbance may be reported with systemic and topical (including, intranasal, inhaled and intraocular) 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 of visual disturbances 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.

Paediatric population:
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.

4.5 Interaction with other medicinal products and other forms of interaction:
No interaction studies have been performed.

4.6 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.

4.7 Effects on ability to drive and use machines:

Betamethasone Dipropionate cream USP has no influence on the ability to drive and use machines.

4.8 Undesirable effects:

Sicacort-BD 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 Sicacort-BD 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.

Vision blurred (see also section 4.4) has been reported with corticosteroid use (frequency not known).

4.9 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:

5.1 Pharmacodynamic properties:

Sicacort-BD 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

6.5 Nature and contents of container:

30 g white coloured soft cream filled in aluminium collapsible tube with HDPE cap packed with a leaflet in a monocarton.

6.6 Special precautions for disposal:

No special instructions needed

7. Marketing Authorization Holder

Registrant:

Name : **Brassica Pharma Pvt. Ltd.**
Address : 7th Floor – Vastubh Apartment,
Off Road to Carter Road No.1,
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Manufacturer:

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8. Marketing Authorization number:

09128/07139/REN/2019

9. Date of first auth rization:

1/12/2016

10. Date of revision of the text:

31/08/2019