# BETASOL LOTION
# (Clobetasol Propionate Topical Solution USP)

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1. NAME OF THE MEDICINAL PRODUCT

**BETASOL LOTION** (Clobetasol Propionate Topical Solution USP)

### 2. QUALITATI VE AND QUANTITATIVE COMPOSITION

| Chemical Name | Approved Name (if any) | Quantity per 30ml bottle in mg | Active / Non - active |
|---|---|---|---|
| 21-Chloro-9-fluoro-11β ,17 dihydroxy16β -methylpregna-1,4-diene 3,20-dione 17-propionate | Clobetasol Propionate USP | 15.00 | Active Ingredient |
| **Excipients** | | | |
| Propane-1,2,3-triol | Glycerin BP | 4320.0 | Solvent |
| Methyl 4-hydroxybenzoate | Methyl Hydroxybenzoate BP (Methyl Paraben) | 30.0 | Antimicrobial Preservative |
| Propyl 4-hydroxybenzoate | Propyl Hydroxybenzoate BP (Propyl Paraben) | 15.0 | Antimicrobial Preservative |
| (RS)-propane-1,2-diol | Propylene Glycol BP | 18000.0 | Solvent |
| 2-Hydroxypropane-1,2,3-tricarboxylic acid monohydrate | Citric acid Monohydrate BP | 82.8 | Buffering Agent |
| Trisodium 2 hydroxypropane-1,2,3tricarboxylate dihydrate | Sodium Citrate BP | 130.8 | Buffering Agent |
| ------ | Purified Water BP | q.s to 30 ml | Vehicle |

**Definitions:**

BP: British Pharmacopoeia

USP: United State Pharmacopoeia

### 3. PHARMACEUTICAL FORM

Lotion (Topical Preparation)

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Betasol is indicated for the treatment of the following situations: - Psoriasis (excluding widespread plaque psoriasis); - Resistant forms of eczema; - Contact dermatitis; - Seborrheic dermatitis; - Lichen planus; - Discoid lupus erythematosus; other dermal conditions that do not respond satisfactorily to less active steroids.

## 4.2 Posology and method of administration

Apply the minimum amount necessary to the affected area once or twice a day. Discontinue therapy when it obtains control of the situation. Treatment should not continue for more than 4 weeks without the patient being reassessed. Betasol can be used in treatment cycles repeated short-term to control exacerbations. If continuous steroid treatment is required, use a less potent formulation. Betasol is potent, so treatment should be limited to two consecutive weeks and amounts not greater than 50g a week should be used because of the potential that the drug has to suppress the hypothalamic- pituitary- adrenal. If necessary, in very resistant lesions, especially in case of hyperkeratosis, the anti- inflammatory action of Betasol may be enhanced by occlusion of the area to be treated with a polyethylene film. It is usually sufficient for an occlusion overnight to yield a satisfactory response, and the improvement attained can be kept up with topical application without occlusion.

Betasol Lotion: Apply a few drops of lotion Betasol the affected area and massage until completely absorbed.

**Route of Administration:** Lotion (Topical Preparation)

## 4.3 Contraindications

Betasol is contraindicated in the following situations: Hypersensitivity to the active substance or to any of the excipients; rosacea; acne vulgaris; perioral dermatitis; perianal and genital pruritus; Primary cutaneous viral infections (e.g. Herpes simplex, chickenpox); treatment of primary cutaneous lesions caused by fungi or bacteria; dermatoses in children under 12 years of age, including dermatitis and rash caused by diapers.

The long-term therapy is contraindicated in patients with diabetes mellitus or tuberculosis.

## 4.4 Special warnings and precautions for use

**Pregnancy -** Betasol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing mothers -** Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing woman.

**Paediatric Use-** HPA axis (hypothalamic-pituitary-adrenal axis) suppression, Cushing's syndrome and intracranial hypertension have been reported in paediatric patients receiving topical corticosteroids.

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

None have been reported on local application. Avoid using other topical medications, harsh or abrasive soaps, or cosmetics on the affected area.

## 4.6 Pregnancy and lactation

**Use in Fertility-** There are no data in humans to evaluate the effect of topical corticosteroids on fertility

**Use in Pregnancy -** Betasol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Use in nursing mothers -** In nursing mothers systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing woman.

## 4.7 Effects on ability to drive and use machines

Not applicable

## 4.8 Undesirable effects

Local hypersensitivity reactions may occur such as erythema, rash, pruritus, urticaria, itching and located allergic contact dermatitis that may resemble the symptoms of the disease. If signs of hypersensitivity reactions should be discontinued immediately the application. Effects of hypercortisolism. Like other topical corticosteroids, prolonged use of large amounts or treatment may result in large areas sufficient to produce the effect of systemic absorption hypercortisolism. This effect is most likely to occur in infants and children, and if used with occlusive dressings. In infants, the diaper may act as an occlusive dressing.

In adults, providing that total less than 50 g weekly dose. Prolonged and intensive treatment with very potent formulations of corticosteroids can cause dilation of superficial blood vessels, particularly when occlusive dressings are used or skin folds are involved. Local atrophy, striae, thinning, pigmentation changes, hypertrichosis, exacerbation of symptoms underlying pustular psoriasis. Prolonged and intensive treatment with very potent formulations of corticosteroids can cause local atrophic changes such as thinning, stretch marks, particularly when used dressings or skin folds are involved. It is suspected that, in very rare cases, the treatment of psoriasis with corticosteroids (or its suspension) have provoked the pustular form of the disease.

## 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.

# 5. PHARMACOLOGICAL PROPERTIES

**Pharmacological category:** Corticosteroids, very potent (group IV)

**ATC Code:** D07AD

## 5.1 Pharmacodynamic properties

Betasol is local anti-inflammatory drug acting on skin and mucous membranes. Betasol acts by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

## 5.2 Pharmacokinetic properties

The percutaneous penetration of clobetasol propionate vary individually and can be increased by the use of occlusive dressings, or when the skin is inflamed or damaged. In a study of healthy individuals and healthy skin, the mean maximum plasma concentration of clobetasol propionate 0.63 mg / ml occurred eight hours after the second application (13 hours after initial application) 30 g of ointment clobetasol propionate 0.05%

After application of a second dose of 30 g of Clobetasol propionate cream 0.05%, the mean maximum plasma concentration was slightly higher than that of the ointment and took place 10 hours after application. In another study , the mean maximum plasma concentration was about 2.3 mg / ml and 4.6 ng / ml in patients with psoriasis and eczema , respectively, and was 3 hours after a single application of 25 g ointment propionate Clobetasol 0.05%. Upon the percutaneous absorption of clobetasol propionate ,probably the drug followed the metabolic pathway of systemically administered corticosteroids. However, clobetasol systemic metabolism is not fully characterized or quantified.

## 5.3 Preclinical safety data

**N Carcinogenesis**

Long-term animal studies have not been performed to evaluate the carcinogenic potential of Clobetasol propionate.

**Genotoxicity**

Clobetasol propionate was not mutagenic in a range of *in vitro* bacterial cell assays.

**Reproductive Toxicology**

**Fertility**

In fertility studies, subcutaneous administration of clobetasol propionate to rats at doses of 6.25 to 50 micrograms/kg/day produced no effects on mating, and fertility was only decreased at 50 micrograms/kg/day.

**Pregnancy**

Subcutaneous administration of clobetasol propionate to mice (=100 micrograms/kg/day), rats (400 micrograms/kg/day) or rabbits (1 to 10 micrograms/kg/day) during pregnancy produced foetal abnormalities including cleft palate and intrauterine growth retardation.

In the rat study, where some animals were allowed to litter, developmental delay was observed in the F1 generation at =100 micrograms/kg/day and survival was reduced at 400 micrograms/kg/day. No treatment related effects were observed in F1 reproductive performance or in the F2 generation.

## 6.1 List of excipients

Glycerin BP
Methyl Hydroxybenzoate BP (Methyl Paraben)
Propyl Hydroxybenzoate BP (Propyl Paraben)
Propylene Glycol BP
Citric acid

Monohydrate BP
Sodium Citrate BP
Purified Water BP

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

36 months (3 Years)

## 6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

## 6.5 Nature and contents of container

White 30ml LDPE & HDPE bottle with Nozzle (LDPE) & Cap (HDPE). Such single filled and sealed bottle packed in carton along with pack insert.

## 6.6 Special precautions for disposal and other handling

Patients should be advised to wash their hands after applying Clobetasol propionate.

## 7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC,

30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

## 8. MARKETING AUTHORISATION NUMBER

The product Betasol Lotion is registered in DRC, CAR, Ghana, Zambia, Kenya

## 9. DATE OF UPDATE OF TEXT

Every two years.