1. **Name of the Medicinal Product**

   3 – BETA CREAM

2. **Qualitative and Quantitative Composition**

   Each gram contains

Clobetasol Propionate BP	0.05% w/w
Miconazole Nitrate BP	2.0% w/w
Neomycin Sulphate BP	0.50% w/w
Cream Base	q.s

3. **Pharmaceutical Form**

   Cream for topical administration

4. **Clinical Particulars**

4.1 Therapeutic Indications

Antifungal; Antibacterial; Anti-inflammatory, Topical

3-Beta Cream cream effectively controls inflammatory disorders superadded with bacterial and fungal infections of the skin.

4.2 Posology and Method of Administration

Gently massage sufficient Cream into the affected skin areas twice a day, in the morning and evening Cream should not be used longer than 2 weeks in the treatment of tinea corporis or tinea cruris, and amounts greater than 45 g per week of cream or amounts greater than 45 mL per week. If a patient with tinea corporis or tinea cruris shows no clinical improvement after 1 week of treatment with Cream the diagnosis should be reviewed.

Cream should not be used longer than 4 weeks in the treatment of tinea pedis and amounts greater than 45 g per week of Cream or amounts greater than 45 mL per week. If a patient with tinea pedis shows no clinical improvement after 2 weeks of treatment with Cream diagnosis should be reviewed. Cream or Lotion should not be used with occlusive dressings.

Contraindications

Hypersensitivity to Clobetasol Propionate, Neomycin sulfate and Miconazole Nitrate or to any of the excipients of 3-Beta Cream.

4.4 Special Warnings and Precautions for use

None Known

4.5 Interactions with other medicinal products and other forms of interactions

No clinically significant interactions have been identified

4.6 Fertility, Pregnancy and Lactation

Pregnancy

No clinical interactions available. However, 3-Beta Cream should only be used as per the advice of the Physician

Lactation

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Cream or Lotion is administered to a nursing woman

4.7 Effects on ability to drive and use machines

No effects seen

4.8 Undesirable Effects

Possible sensitivity reactions including drying, redness, rash and irritation

4.9 Overdose

Signs and Symptoms

Amounts greater than 45 g/week of Cream or 45 mL/week of cream should not be used. Acute overdosage with topical application of Cream is unlikely and would not be expected to lead to a life-threatening situation. Cream should not be used for longer than the prescribed time period.

Topically applied corticosteroids, such as the one contained in Cream can be absorbed in sufficient amounts to produce systemic effects

5. Pharmacological Properties

3-BETA cream provides a comprehensive treatment for various inflammatory dematological disorders superadded with bacterial or superficial fungal infections of the skin. Clobetasol Propionate is one of the most potent topical corticosteroid available and rapidly controls the symptoms such as itching, redness and swelling.

Miconazole Nitrate is a broad spectrum synthetic antifungal agent which has fungicidal action against all the fungi responsible for superficial fungal infections of the skin. Neomycin sulfate is a broad spectrum antibacterial.

5.1 Pharmacokinetics

Clobetasol Propionate is one of the most potent topical corticosteroid available and rapidly controls the symptoms such as itching, redness and swelling.

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

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

Studies performed with Cream indicate that these topical combination antifungal/corticosteroids may have vasoconstrictor potencies in a range that is comparable to high-potency topical corticosteroids. Therefore, use is not recommended in patients less than 17 years of age, in diaper dermatitis, and under occlusion

5.2 Pre-Clinical Safety Data

No other information relevant to the prescriber other than that already stated in other sections of the SPC.

6. Pharmaceutical Particulars

6.1 List of Excipients

Propylene Glycol
Parachlorometacresol
Light Liquid Paraffin
White petroleum Jelly
Benzyl Alcohol
Ceto Stearyl Alcohol
Ceto Macrogol 1000
Tween -80
Di-sodium EDTA

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 months from the Date of Manufacture

6.4 Special precautions for Storage

Store below 25°C

6.4 Nature and contents of Container

30 gm lami Tube packed in an monocarton along with insert.

6.5 Special precautions for disposal:

NA

7. Marketing Authorization Holder

NA

8. Manufactured By:

Merit Organics Ltd
Plot No 2104/2/A , G.I.D.C , Sarigam , Bhilad, Dist Valsad-396155 Gujarat INDIA

9. Date of First Authorisation/Renewal of Authorisation

NA