

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

1.1 Name of the Medicinal Product

BASEHEAL

(Ketoconazole, Clobetasol Propionate & Neomycin Sulphate Cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Ketoconazole BP	10 mg
Clobetasol Propionate BP	0.25 mg
Neomycin Sulfate BP	5000 IU
Cream base	q.s.

3. PHARMACEUTICAL FORM

White to off white Colour Smooth Lumps Free Cream

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

BASEHEAL is indicated for the topical treatment of fungal infections of the skin including: Tinea Cruris, Tinea Corporis; tinea manus, tinea pedis, and so on.

4.2. Posology and method of administration

Topical application.

Apply to the affected area two or three times daily. Generally, the duration of application depends on the type of infecting organism. Treat as below for the following: Tinea orporis 2 weeks, Tinea Cruris 2 weeks, Tinea Manus 4 weeks, Tinea Pedis 4 weeks.

4.3. Contraindications

BASEHEAL is contra-indicated in the patients with known hypersensitivity to any of its active ingredients, BASEHEAL is for topical use only and cannot be used for internal or ophthalmic use.

4.4. Special warnings and special precautions for use

Avoid contacting with eyes.

- Patients with tinea cruris avoid wearing underwear that is tight-fitting or made from synthetic materials (e.g., rayon, nylon). Instead, wear loose-fitting, cotton underwear.
- Patient with tinea pedis avoids wearing socks made from wool or synthetic materials (for example, rayon or nylon). Instead, wear clean, cotton socks and change them daily or more often if your feet sweat a lot. Wear well-ventilated shoes.
- If your skin problem does not improve within 2-4weeks for cutaneous candidiasis, pityriasis versicolor, tinea corporis, or tinea cruris; or 4 weeks for scborrheic dermatitis; or if it becomes worse, check with your doctor,
- BASEHEAL contains Clobetasol Propionate. If the product is administered for long term in large area or used with banding treatment it may induce the reversibility restraint of PHA axis. Cushing syndromes, hyperglycosemia, urinary glucose etc. can be occurred on some patents. So long term and large area using the product is not recommended. Banding treatments is not recommended too.
The product can be used in the cockled skin of the face, armpit and groin under the supervision of a medical doctor.
- Combining with other skin infection, the anti-infective drugs should be administrated. If the infection has not been controlled, stop using the product until the infection is controlled.
- When the local Ulcer and damage occur, Neomycin Sulfate is absorbed increasingly. The adverse reaction of aminoglycoside drug should be observed.

4.5. Interactions with other Drug products and other forms of interaction

BASEHEAL as a topical cream dose not interacts with any other product.

4.6 Pregnancy and lactation

- Pregnant and lactation women should be used with caution.
- Large arca and long-term using is not recommended.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Erythema, burning, itch, sharp pain or other stimulus symptom, folliculitis, skin atrophy, capillarectasis, etc are commonly seen.

- Skin dryness, pilosis polytrichia, striac atrophicac and infectious susceptibility increasing can be observed.
- Adrenocortical hyperfunction can be induced by long-term using. The symptom includes pilosis polytrichia, acne, moon face, Osteoporosis, etc.
- Allergic contact dermatitis can be seen on occasion.

4.9 Overdose

BASEHEAL is well tolerated, no adverse effect has been observed in the event of overdosage.

5. Pharmacological properties

5.1. Pharmacodynamic properties

The active ingredient of BASEHEAL is ketoconazole, a pyrrolidine antifungal agent. It has extremely potent anti-mycotic actions against dermatophytes and yeasts (candidiasis, Pityrosporum sabour, Torulopsis, Cryptococcus), histoplasmosis capsulalum, Eumycetes. However the product has weak inhibitory action to Aspergillus, Sporothrix schenckii, dematiaceous fungi and mucor except for Entomophthorales.

Action mechanism of Ketoconazole: it can selectively inhibit the cytochromes P-450 activity of fungi. Therefore, the Biosynthesis of Ergosterol on the cell membrane inhibited. Clobetasol Propionate is a hormone of the cortex that is highly effective anti-inflammatory and cause capillary contraction. Neomycin Sulfate, external use aminoglycoside antibiotics, can treat local infection,

5.2 Pharmacokinetic Properties

Ketoconazole which is applied to the chest, back and buttocks of the healthy volunteers can not be inspected in blood (Detectable Limit is less than Smg/ml) during the first 7 hours. Clobetasol Propionate can be completely absorbed by dermal. The administered dose is metabolized, primarily in the liver. And it is excreted by kidney. Neomycin Sulfate can be rarely absorbed by derma. However, when the skin is ulcer and breakage it can be absorbed increasingly.

5.3. Preclinical safety data

None known.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Propylene Glycol
CetoStearyl Alcohol
Cetyl Alcohol
Sorbitan Stearate
Polysorbate 60
Isopropyl Myristate
Sodium Sulphite Anhydrous (E221)
Polysorbate 80
Purified Water

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 Months

6.4 Special precautions for storage

Do not store above 30°C, Protect from light.

6.5. Nature and contents of container

1 x 15 gm lami tube

6.6. Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Base Medico Pvt. Ltd.,
Survey No. 570, Village Tundav, Tal. Savli,
Dist. Vadodara - 391775, Gujarat, India.

8. DRUG PRODUCT MANUFACTURER

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9. NAFDAC REGISTRATION NUMBER(S)

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