

1.3.1 Summary of product characteristics

1 Summary of Product Characteristic (Product Data Sheet)

1.1 Name of the Medicinal Product

(a) Product Name: Ketoconazole + Clobetasol Propionate + Neomycin Sulfate

(b) Strength : Ketoconazole USP10 mg
Clobetasol propionateUSP 0.25 mg
Neomycin sulfate USP.....5000 IU

(c) Pharmaceutical Dosage Form : Cream

1.2 Quality and Quantitative Composition

(a) Qualitative Declaration, the active substance should be declared by its recommended INN. Accompanied by its salt or hydrate form if relevant.

Each gm contains:

Ketoconazole USP 10 mg.
Clobetasol propionate USP.....0.25 mg.
Neomycin sulfate USP.....5000 IU

(b) Quantitative Declaration, the quantity of the active substance must be expressed per dosage unit

Sr. No.	Name of the Materials	Specification	Label Claim	Qty/gm
1	Ketoconazole	USP	10 mg	10.00 mg
2	Clobetasol propionate	USP	0.25 mg	0.250 mg.
3	Neomycin sulfate	USP	5000 IU	7.788 mg.

1.3 Pharmaceutical Form Visual description of the appearance of the product (colour, markings, etc.) e.g:

Milky white colored cream filled in Printed lami tube & Sealed with milky white colored plastic cap. Each 15gm Lami tube packed in a Printed carton with Leaflet.



1.4 Clinical Particulars

(a) Therapeutic indications:

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

(b) 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.

(c) Contraindications:

Skinmed Cream is contra-indicated in the patients with known hypersensitivity to any of its active ingredients. Skinmed Cream is for topical use only and can not be used for internal or ophthalmic use.

(d) Special warning and 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 seborrheic dermatitis; or if it becomes worse, check with your doctor.
- Skinmed Cream 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.

(e) Interaction with other medicinal products and other forms of interactions:

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

(f) Pregnancy and lactation:

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

(g) Effects on ability to drive and use machine:

None

(h) Undesirable effects:

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

- Skin dryness, pilosis polytrichia, striae atrophicae 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.

(i) Overdose:

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

1.5 Pharmacological Properties

Pharmacodynamic Properties:

The active ingredient of Skinmed Cream 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.

(b) 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 5mg/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.

(c) Preclinical Safety Data:

None

1.6 Pharmaceutical Particulars

(a) List of excipients:

Mineral Oil USP
White petrolatum USP
Cetostearyl alcohol USP
Ceto macrogol - 1000 IHS
Propylene glycol USP
Chlorocresol USP
Monobasic sodium phosphate USP
Purified water USP

(b) Incompatibilities:

None

(c) Shelf life: 36 Months

(d) Special precautions for storage: Store in a cool dry place, away from light. Avoid contact with eyes.

Keep out of the reach of children.

KWALITY PHARMACEUTICALS LTD.
Vill. Nag Kalan, Majitha Road, Amritsar- 143601.
INDIA

PRODUCT: SKINMED CREAM
(Ketoconazole + Clobetasol Propionate
+ Neomycin Sulfate)



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(e) Nature and contents of container: Printed lami-tube

1.7 Marketing Authorization Holder