



Module 1 Administrative and Product Information

SKIGUD CREAM

Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream

1.3 PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the Medicinal Product

Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream.

2. Qualitative and Quantitative Composition

Each gram contains:

Ketoconazole USP.....10 mg
Clobetasol Propionate USP.....0.25 mg
Neomycin Sulfate USP.....5000 IU
Cream Base.....Q.S.

3. Pharmaceutical Form

Cream.

4. Clinical Particulars

4.1 Therapeutic Indications

Ketoconazole, Clobetasol Propionate and Neomycin Sulfate 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.

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 Corporis: 2 Weeks

Tinea Cruris: 2 Weeks

Tinea Manus: 4 Weeks

Tinea Pedis: 4 Weeks



4.3 Contraindications

Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream, is contraindicated in the patients with known hypersensitivity to any of its active ingredients.

Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream is for topical use only and cannot be used for internal or ophthalmic use.

4.4 Special Warnings 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 2-4 weeks 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.
- Ketoconazole, Clobetasol Propionate and Neomycin Sulfate 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, hyperglycosenua, urinary glucose etc. can be occurred on some patients. 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.
- Combing 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 Interaction with Other Medicinal Products and Other Forms of Interaction

Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream, is a topical cream Hence, does not interacts with any other products.

4.6 Pregnancy and Lactation

Pregnant and lactation women should be used with caution.

Large area and long term using is not recommended.

4.7 Effects on Ability to Drive and Use Machines

Not known.

4.8 Undesirable Effects

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

- Skin dryness, pilosis polytrichis, 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.

4.9 Overdose

Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream, is well tolerated, no adverse effect has been observed in the event of over dosage.



5. Pharmacological Properties

5.1 Pharmacodynamic Properties

The active ingredient of Ketoconazole, Clobetasol Propionate and Neomycin Sulfate Cream is Ketoconazole, a Pyrrolidone 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, dermatiaceous fungi and mucor except for entomophyhorales.

Mechanism of Action

Ketoconazole: It can selectively inhibit the cytochromes P-450 activity of fungi. Therefore, the biosynthesis of Ergosterol on the cell membrane inhibited.

Clobetasol propionate It is a hormone of the cortex that is highly effective anti-inflammatory and cause capillary contraction.

Neomycin sulfate It is external use aminoglycoside antibiotics, can treat local infection.

5.2 Pharmacokinetic Properties

Ketoconazole It is applied to the chest, back and buttocks of the healthy volunteers cannot be inspected in blood (Detectable Limit is less than 5 mg/ml) during the first 7 hours.

Clobetasol Propionate It can be completely absorbed by dermal. The administered dose is metabolized, primarily in the liver and is excreted by kidney.

Neomycin Sulfate:It can be rarely absorbed by derma. However when the skin is ulcer and breakage it can be absorbed increasingly.

5.3 Preclinical Safety Data

Not known.



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6. Pharmaceutical Particulars

6.1 List of Excipients

Benzyl Alcohol, Cetostearyl Alcohol, Self-Emulsifying Glyceryl Monostearate, Cetomacrogol Emulsifying Wax, Silicone Oil, White Soft Paraffin, Light Liquid Paraffin, Methyl Paraben, Propyl Paraben, Propylene Glycol, Disodium Edetate, Sodium Acid Phosphate, Sodium Phosphate, Rose Flavor, Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special Precautions for Storage

Store below 30°C in cool and dry place, Protect from light.

KEEP ALL MEDICINES AWAY FROM CHILDREN

6.5 Nature and Contents of Container

1 SKIGUD CREAM (30 gm Lamitube) packed in inner carton. Such 10 SKIGUD CREAM (Each of 30 gm Lamitube) in outer carton.

6.6 Special Precautions for Disposal and Other Handling

Not applicable.