

1.3.1	
-------	--

1 summary of Product Characteristics

1.1 Name of the Medicinal Product

(a) Product Name: **NUSKYN** (Ketoconazole + Clobetasol Propionate +Neomycin)

(b) Strength

Ketoconazole USP10 mg
Clobetasol Propionate USP 0.25 mg
Neomycin USP..... 5000 IU

(c) Pharmaceutical Dosage Form : Cream

1.2 Quality and Quantitative Composition

(a) Qualitative Declaration, the active susstance 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 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	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 & scaled with milky white colored plastic cap. Each 15gm Lami tube packed in a Printed carton with Leaflet.

1.4 Clinical Particulars

(a) Therapeutic indications:

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

(b) Posology and method of administration:

Topical application.

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

(c) Contraindications:

Nuskyn cream is contra indicated in the patients with known hypersensitivity to any of its active ingredients. Nuskyn Cream is for tropical use only and cannot be used for internal or ophthalmic use.

(d) Special warning and precaution 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.
- Patients with tinea pedis avoids wearing socks made from wool or synthetic materials (for example, rayon, 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 improves with-in 2-4weeks for cutaneous candidiasis, pityriasis versicolor, tinea corporis, or tinea cruris; 4 weeks for seborrheic dermatitis; or if it becomes worse, check with your doctor.
- Nuskyn 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 retrain of PHA axis. Cushing syndromes, hyperglycosemia, 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.
- Combining with other skin infection, the anti-infective drugs should be administered. If the infection has not been controlled, stop using the product until the infection is controlled.
- When the local ulcer and damage occur, Neomycin is absorbed increasing. The adverse reaction of aminoglycoside drug should be observed.
-

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

Nuskyn cream as a topical cream dose not interaction with ant other product.

(f) Pregnancy and lactation:

- Pregnant and lactation women should use 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 susceotibility increasing can be observed.

- Adrenocortical hyperfunction can be introduced by long term using. The symptom includes pilosis polytrichia, acne, moon face, Osteoporosis, etc.
- Allergic contact dermatitis can be seen on occasion.
-

(i) Overdose

Nuskyn 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 Nuskyn Cream is ketoconazole, a pyrrolidine antifungal agent. It has extremely potent anti-mycotic actions against dematophytes and yeasts (candidiasis, pityrosporum sabour, Torulopsis, Cryptococcus), histoplasmosis capsulalum, Eumycetes. However the product has weak inhibitory action to Aspergillus, Sporothrix schenckii, dematiaceous fungi and muccor except for Emtomophthorales.

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 Peopionate is a hormone of the cortex that is highly effective anti-inflammatory and cause capillary contraction. Neomycin, external use amininoglycoside antibodies, can treat local infection.

(b)Pharmacokinetic Properties:

Ketoconazole which is applied to the chest, back and buttock of the healthy volunteers can not be inspected in blood (Detectable limit is less than 5mg/gl) during the first 7 hours. Clobetasol Propionate can be completely absorbed by dermal. The administered dose is metabolized, primarily in the liver. And is excreted by kidney. Neomycin cn 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 petroleum USP
Ctostearyl alcohol USP
Propylene glycol USP
Ceto macrogol – 1000IHS
Chlore cresol 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

Manufactured by:

Zhejiang Jingwei Pharmaceutical. Co., LTD.
Changhan Industrial Park, Zhejiang Province, China

Marketed by:

Sam Sunny Pharmacy and Stores Limited
#183 Ojo-Igbede Road Ajangbandi, Ojo L.G.A Lagos State, Nigeria.

