

NUCREST CREAM
(Ketoconazole, Clobetasol Propionate Neomycin Sulfate Cream)

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

NUCREST CREAM

(Ketoconazole, Clobetasol Propionate Neomycin Sulfate Cream)

2. Qualitative and quantitative composition

Each Gram Contains :

Ketoconazole USP..... 10.0mg

Clobetasol Propionate USP..... 0.25mg

Neomycin Sulfate USP.... 5000.00 IU

Perfume IHS..... Q. S.

Cream Base Q.S

3. Pharmaceutical form

Cream

4. Clinical particulars

4.1 Therapeutic indications

Ketoconazole has a potent antimycotic action against dermatophytes and yeasts. Ketoconazole cream acts rapidly on the pruritus, which is commonly seen in dermatophyte and yeast infections. This symptomatic improvement often occurs before the first signs of healing are observed.

Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.

Neomycin is a rapidly bactericidal aminoglycoside antibiotic effective against Gram positive organisms including staphylococci and a wide range of Gram negative organisms. Strains of *Pseudomonas aeruginosa* are resistant to neomycin, as are fungi and viruses.

4.2 Posology and method of administration

Posology

Apply to the affected area once a day, depending on the severity of the infection, the cream may be applied on the affected area twice daily when necessary. Generally the duration of application depends on the type of infecting organism; Treat as follows for the following: Tinea Corporis 2 weeks; Tinea Cruris 2 weeks; Tinea Pedis 4 weeks; Tinea Manus 4 weeks.

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Infection normally resistant to antifungal agents 4-6 weeks.

Method of administration

Topical administration only.

4.3 Contraindications

NUCREST cream is contraindicated in patients with known hypersensitivity to any of its ingredients. NUCREST cream is for topical use only and cannot be used for internal or ophthalmic use. Special precautions must be observed during use on pregnant women and children.

4.4 Special warnings and precautions for use

Warning: For external use only, Avoid contact eyes, Do not exceed prescribed dosage, Read carefully before using.

Precautions: Application to the face or on large areas for longer periods of time than recommended in leaflet should be under a medical doctor's supervision.

4.5 Interaction with other medicinal products and other forms of interaction

NUCREST cream as a topical cream does not interact with any other product.

4.6 Pregnancy and lactation

There are no known risks associated with the use of NUCREST cream in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

NUCREST cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

NUCREST cream is topical antifungal cream that is well tolerated and has little or no side effects when used properly. On occasion, irritation or burning sensation may occur during treatment. However it is unnecessary to discontinue treatment with NUCREST cream.

In severe or extreme cases you may contact the doctor.

4.9 Overdose

NUCREST cream is well tolerated, no adverse effect has been observed in the event of over dosage.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungal, Corticosteroid, Antibacterial

Pharmacotherapeutic classification:

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Clobetasol propionate is a highly active corticosteroid with topical anti-inflammatory activity. The major effect of clobetasol propionate on skin is a non-specific anti-inflammatory response, partially due to vasoconstriction and decrease in collagen synthesis.

Neomycin is a rapidly bactericidal aminoglycoside antibiotic effective against Gram positive organisms including staphylococci and a wide range of Gram negative organisms. Strains of *Pseudomonas aeruginosa* are resistant to neomycin, as are fungi and viruses. Pharmacokinetic properties

Plasma concentrations of ketoconazole were not detectable after topical administration of ketoconazole cream in adults on the skin. In one study in infants with seborrhoeic dermatitis (n = 19), where approximately 40 g of ketoconazole cream was applied daily on 40 % of the body surface area, plasma levels of ketoconazole were detected in 5 infants, ranging from 32 to 133 ng/mL.

Percutaneous penetration of clobetasol propionate varies among individuals and can be increased by the use of occlusive dressings, or when the skin is inflamed or diseased.

Neomycin is either not absorbed or is absorbed only minimally through intact skin. Any neomycin which is absorbed will be rapidly excreted by the kidneys in an unchanged state

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5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

6 Pharmaceutical particulars

6.1 List of excipients

1. Chlorocresol BP
2. Cetostearyl Alcohol BP
3. Macrogol cetostearyl ether BP
4. Butylated Hydroxy Anisole BP
5. Butylated Hydroxy Toluene BP
6. White soft Paraffin BP
7. Sodium Dihydrogen Phosphate Dihydrate BP
8. Disodium Hydrogen Phosphate Dihydrate BP
9. Light Liquid Paraffin BP
10. Propylene Glycol BP
11. Disodium EDTA BP
12. Perfume IHS
13. Purified Water BP

a. Incompatibilities

None known

b. Shelf life

3 years

c. Special precautions for storage

Store below 30⁰C in dry place. Protect from Sunlight.

d. Nature and contents of container

30 g tube in a mono carton.

e. Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

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7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

Name and address of Manufacturing Site:

GOPALDAS VISRAM & COMPANY LIMITED

Plot No. : A / 590-591, T.T.C. Industrial Area, M.I.D.C.,

Mahape, Navi Mumbai – 400 710, India.

Telephone : 91-22-41111710 / 717

E-Mail: sangeetajagani@gopaldasvisram.com

8. Marketing Authority

SUITLEIFE PHARMACEUTICALS LTD.

4, Ayo, Davies Close, Off Ekololu Street,

Surulere, Lagos State, Nigeria.