

SMPC FOR JESSKIN TRIPLE ACTION CREAM

1. Name of The Medicinal Product

Jesskin triple action cream

2. Qualitative and Quantitative Composition

Ketoconazole BP

Clobetasol Propionate

Neomycin sulphate

3. Pharmaceutical Form

Topical Cream

4. Clinical particulars

4.1 Therapeutic indications

Jesskin Triple Action Cream contains a medicine called ketoconazole, Clobetasol Propionate and Neomycin sulphate. This belongs to a group of medicines called 'antifungals, antibacterial and anti-inflammatory'. (Triple action)

Jesskin Triple Action Cream is indicated in patients 12 years and older for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris and tinea corporis due to Epidermophyton floccosum, Trichophyton mentagrophytes, and Trichophyton rubrum. Effective treatment without the risks associated with topical corticosteroid use may be obtained using a topical antifungal agent that does not contain a corticosteroid, especially for non-inflammatory tinea infections. The efficacy of Jesskin Triple Action Cream for the treatment of infections caused by zoophilic dermatophytes (e.g., Microsporum canis) has not been established. Several cases of treatment failure of Jesskin Triple Action Cream in the treatment of infections caused by Microsporum canis have been reported. Neomycin sulphate is a broad -spectrum antibiotic agent effective against gram-negative & gram positive organisms, although it is not effective against Pseudomonas aeruginosa.

4.2 Dosage and method of administration

Cutaneous candidiasis, tinea corporis, tinea cruris, tinea pedis and tinea (pityriasis) versicolor: It is recommended that Jesskin be applied once daily to cover the affected and immediate surrounding area. Clinical improvement may be seen fairly soon after treatment is begun; however, candidal infections and tinea cruris and corporis should be treated for two weeks in order to reduce the possibility of recurrence. Patients with tinea versicolor usually require two weeks of treatment. Patients with tinea pedis require six weeks of treatment. Seborrheic dermatitis: Jesskin Triple Action Cream should be applied to the affected area twice daily for four weeks or until clinical clearing.

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If a patient shows no clinical improvement after the treatment period, the diagnosis should be redetermined.

4.3 Contraindications

Jesskin Triple Action Cream is contraindicated in persons who have shown hypersensitivity to the active or excipient ingredients of this formulation.

4.5 Special warnings and precautions for use

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Conditions which augment systemic absorption include use over large surface areas, prolonged use, and use under occlusive dressings. Use of more than one corticosteroid-containing product at the same time may increase total systemic glucocorticoid exposure. Patients applying Jesskin triple action cream to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA-axis suppression. This may be done by using the ACTH stimulation, morning plasma cortisol, and urinary free cortisol tests.

If HPA-axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs

Children and adolescents:

Jesskin Triple Action Cream is not recommended for use in children under 12 years of age.

Other medicines and Jesskin Triple Action Cream

Jesskin Triple Action Cream does not normally react with other medicines. However, tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

Pregnancy and breast-feeding:

Jesskin Triple Action Cream can be used if you are pregnant or breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breastfeeding.

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Personal hygiene:

- Unless the affected skin is on your hands, wash your hands with soap and water after using the cream
- Washing your hands after using the cream will stop you spreading the infection to other parts of your body or to other people
- Do not allow other people to use your flannel or towel. This will stop them from getting your infection
- Clothing that touches infected skin should be washed and changed often.

5. Interaction with other medicinal products and other forms of interaction

Not Applicable.

5.1 Undesirable effects

Side Effects includes:

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Jesskin Triple Action Cream and tell your doctor straight away if you notice or suspect any of the following. You may need urgent medical treatment.

- Severe irritation or reddening of the skin where the cream has been used or other signs of allergy during the first few days of treatment. This can affect fewer than 1 in 10 people
- Peeling or blistering of the skin. This can affect fewer than 1 in 100 people

Tell your doctor or pharmacist if you notice or suspect any of the following side effects:

Common side effects (affects fewer than 1 in 10 people)

- Burning sensation

Uncommon side effects (affects fewer than 1 in 100 people)

- Problems where the cream has been used such as:
 - Bleeding
 - Discomfort
 - Dryness
 - Inflammation (contact dermatitis)
 - Tingling
- Rash, hives (also known as nettle rash or urticaria)
- Sticky skin

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5.3 Overdose

Not Applicable

6. PHARMACOLOGICAL PROPERTIES

a. Pharmacodynamics properties

Ketoconazole

In studies of the mechanism of action in fungal cultures, the minimum fungicidal concentration of Ketoconazole caused leakage of intracellular phosphorous compounds into the ambient medium with concomitant breakdown of cellular nucleic acids, and accelerated potassium efflux. Both of these events began rapidly and extensively after addition of the drug to the cultures.

Neomycin sulphate

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.

Clobetasol propionate

Corticosteroids bind to the glucocorticoid receptor, inhibiting pro-inflammatory signals, and promoting anti-inflammatory signals. Clobetasol propionate is generally applied twice daily so the duration of action is long. Corticosteroids have a wide therapeutic window as patients may require doses that are multiples of what the body naturally produces. Patients taking corticosteroids should be counselled regarding the risk of hypothalamic-pituitary-adrenal axis suppression and increased susceptibility to infections.

b. Pharmacokinetic properties

The absorbance of ketoconazole from the gastrointestinal tract is variable and increases with decreasing stomach pH. It is recommended that ketoconazole is given with food to increase absorption and reduce gastrointestinal disturbances, although reduced rate and extent of absorption have occurred when given after a meal. Mean peak plasma concentration of about 3.5 µg per ml have been obtained 2 hours after administration of 200 mg by mouth. After systemic application, ketoconazole is not systematically absorbed and does not produce detectable plasma concentrations. Ketoconazole is more than 90 % bound to plasma proteins, mainly albumin. It is widely distributed and appears in breast milk. Penetration into the CSF is poor. The elimination of ketoconazole is reported to be biphasic, with an initial half-life of 2 hours and a terminal half-life of about 8 hours.

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Neomycin

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.

Ketoconazole is metabolized in the liver to inactive metabolites. It is excreted as metabolites and unchanged drug chiefly in the faeces; some is excreted in the urine.

c. Preclinical safety data

Not Applicable.

7. Pharmaceutical Particulars

a. Incompatibilities

None known

b. Shelf life

36 Months

c. Special precautions for storage

Store in cool, dry and dark place.

Keep all medicines out of reach of children.

FOR EXTERNAL USE ONLY

d. Nature and contents of container

1 x 30g Tube

e. Special precautions for disposal <and other handling>

No special requirements.

7. Marketing authorisation holder

Jessy Pharmaceutical company Limited

8. Marketing authorisation number(s)

A11-1303

9. Date of first authorisation/renewal of the authorisation

29/09/2022

10. Date of revision of the text

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28/09/2027