1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Triple action cream 15g

2. Qualitative and quantitative composition

Each 1g contains Ketoconazole 10mg, Clobetasol propionate 0.25mg, Neomycin Sulfate 5000IU.

3. Pharmaceutical form

Cream.

4. Clinical particulars

4.1 Therapeutic indications

The product is mainly used for superficial skin fungal infections, such as Tinea mantis, tinea pedis, tinea body, tinea jock and so on.

4.2 Posology and method of administration

It is recommended that Triple action cream can be applied once or twice daily to cover the affected and immediate surrounding area. Tinea corporis and cruris always last for 2 weeks. Tinea mantis, tinea pedis last for 4 weeks.

Treatment should be continued, until a few days after disappearance of all symptoms. The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks of treatment. General measures in regard to hygiene should be observed to control sources of infection or reinfection.

Method of administration: Cutaneous use.

4.3 Contraindications

Triple action cream is contra-indicated in patients with a known hypersensitivity to any of the ingredients.

Viral infections such as herpes and chickenpox are prohibited

Tinea patients should not wear close underwear or chemical fiber underwear, should wear cotton woven loose underwear.

4.4 Special warnings and precautions for use

Triple action cream is not for ophthalmic use. It is better to avoid contact with eyes and other mucous membranes (such as mouth and nose). It is also not suitable for face, armpit, groin, vulva and other thin skin.

People with allergic constitution should use with caution.

For tinea pedis, dry the skin after bath (especially the skin between the toes). Wear cotton socks and change them daily. Shoes should be well ventilated.

If there is burning sensation, redness and swelling at the medication site, the drug should be stopped, and the local drug should be washed, and the serious case should

seek medical treatment in time.

This product contains a strong corticosteroid clobetasol propionate, which is not suitable for long-term, large-scale application, and is not suitable for encapsulation treatment.

Triple action cream contains Cetostearyl Alcohol, which may cause local skin reactions (e.g. contact dermatitis). Also contains propylene glycol which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

None known. If you are using other medicines, please consult your doctor or pharmacist before using this product.

4.6 Pregnancy and lactation

There are no adequate and well-controlled studies in pregnant or lactating women. To date, no other relevant epidemiological data are available. Data on a limited number of exposed pregnancies indicate no adverse effects of Triple action cream on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not relevant to the topical administration of Triple action cream.

Plasma concentration are not detectable after topical application of Triple action cream to the skin of non-pregnant humans. There are no known risks associated with the use of Triple action cream in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

This medicine has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Erythema, burning, itching, tingling or other irritation, hair folliculitis, skin atrophy and thinning, telangiectasia, pigmentation and secondary infections, etc.

Skin becomes dry, hairy, shrunken and susceptible to infection

Long-term use of drugs may cause hypercorticosis, manifested as hypertrichosis, acne, full moon face, osteoporosis and other symptoms.

4.9 Overdose

Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment.

Ingestion

In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Ketoconazole Pharmacotherapeutic Group: Imidazole and triazole derivatives; ATC

code: D01 AC08.

Ketoconazole has a potent antimycotic action against dermatophytes and yeasts. Ketoconazole 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 Pharmacotherapeutic group: Corticosteroids, very potent, dermatological preparations (group IV); ATC code: D07 AD01

Topical corticosteroids act as anti-inflammatory agents via multiple mechanisms to inhibit late phase allergic reactions including decreasing the density of mast cells, decreasing chemotaxis and activation of eosinophils, decreasing cytokine production by lymphocytes, monocytes, mast cells and eosinophils, and inhibiting the metabolism of arachidonic acid. Topical corticosteroids, have anti-inflammatory, antipruritic, and vasoconstrictive properties.

Neomycin Pharmacotherapeutic group: aminoglycoside antibiotic; ATC code: A07AA01.

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.

5.2 Pharmacokinetic properties

Plasma concentrations of ketoconazole were not detectable after topical administration in adults on the skin.

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.

Topical corticosteroids can be systemically absorbed from intact healthy skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier Occlusion, inflammation and/or other disease processes in the skin may also increase percutaneous absorption. They are metabolised, primarily in the liver. Topical corticosteroids are excreted by the kidneys. In addition, some corticosteroids and their metabolites are also excreted in the bile.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics..

6. Pharmaceutical particulars

6.1 List of excipients

Propylene glycol
Liquid paraffin
Cetostearyl Alcohol

Glyceryl monostearate
Ethylparaben
Glycerol
Disodium Edetate
Anhydrous sodium sulfite
Laurocapram
Water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Three years.

6.4 Special precautions for storage
Store below 30 °C.

6.5 Nature and contents of container
Off-white cream in collapsible Aluminum tube.

7. Marketing authorisation holder
DIAMEX HEALTHCARE LTD.
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