Duoskin®

isoconazole nitrate & diflucortolone valerate

1. NAME OF THE DRUG PRODUCT

Duoskin ® Cream, 15g Tube

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of cream contains 1g of diflucortolone valerate and 10 mg isoconazole nitrate. Excipients: White Vaseline - thick paraffin – cetyl stearyl alcohol - polysorbate 60 - sorbitan stearate – Edetate disodium - purified water.

3. PHARMACEUTICAL FORM

Cream for external use

4. CLINICAL PARTICULARS

4.1 Therapeutic indications: It is indicated in the initial treatment of superficial mycotic skin infections characterized by highly inflammatory and eczematous cutaneous events, for example, in the spaces between the fingers and toes, inguinal regions and genital areas. Duoskin is not suitable for the treatment of perioral dermatitis and rosacea.

4.2 Dosage and method of administration: Duoskin is generally applied twice a day to cover the infected area with a thin a layer of the cream with a light massage. In case of infections in the interdigital web spaces of fingers and toes, it is often recommended to apply Duoskin coated gauze between the fingers or toes. Duration of the treatment: the treatment with Duoskin® should be stopped when the symptoms of skin inflammation or eczema improve, but not later than after 2 weeks, and followed, if necessary, by a cream that does not contain corticosteroids. This is especially true for application in inguinal and genital areas.

4.3 Contraindications

• TB (Tuberculosis) and syphilis in the treatment area; virus disease (for eg. after vaccination, in case of smallpox, chickenpox or herpes), acne rosacea, perioral dermatitis.

• Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use: Duoskin® should not come into contact with wounds or mucous membranes. When applying to the face, it must be ensured that Duoskin® does not come into contact with the eyes. The application of topical corticosteroids over large body surfaces or for prolonged periods, especially when an occlusive dressing is applied, significantly increases the risk of side effects. As is the case with corticosteroids for systemic use, glaucoma may also develop with corticosteroids for external use (especially after an extensive application or at high doses over a long period, when using occlusive techniques or when applying to the skin in the eye region). In mixed bacterial infections by Gram negative germs, a specific complementary treatment may be necessary. Regular hygienic measures are very important for an efficient treatment with Duoskin®. In case of athlete's foot, carefully dry the interdigital spaces after washing, and change socks daily. Duoskin® contains a potent corticosteroid, and hence is to be applied only for a short period (in no case, more than two weeks, see «Dosage and administration»). In case of improper use, deterioration of clinical symptoms is possible.

4.5 Interaction with other medicinal products and other forms of interaction: No specific particularities.

4.6 Fertility, Pregnancy and lactation: In principle, during the first 3 months of pregnancy, corticosteroid based preparations for external use should not be used. The potential risks and benefits of the treatment must be carefully weighed during pregnancy and lactation. In particular, an application on a large surface over a long period of time should be avoided. Women who are breastfeeding should not use the cream on their breasts.

4.7 Effects on ability to drive and use machines: No specific particularities

4.8 Undesirable effects: Duoskin® is generally well tolerated; in rare cases, there may be phenomena of skin irritation such as itching, burning sensation, redness or blisters. Applying Duoskin® over a large area (about 10% of the body surface and more) and / or for a long time (more than 4 weeks) can cause local adverse effects such as skin atrophy, telangiectasias, stretch marks and acneiform lesions as well as a systemic action of the corticosteroid due to resorption. As is the case with other corticosteroids for external use, the following adverse reactions may occur in rare cases: folliculitis, hypertrichosis, perioral dermatitis, hypopigmentation, allergic skin reactions to any of the components of the preparation. Neonates whose mothers received the treatment over a large area or for a long time during pregnancy or breastfeeding may also have adverse effects (such as eg decreased adrenocortical function when using it in the last weeks of pregnancy).

4.9 Overdose: There have been no reports about cases of poisoning in humans. Therefore, we cannot advise specific therapeutic measures.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties: Pharmacotherapeutic group: class II corticosteroid, antimycotic. Broad spectrum antifungal to which a corticosteroid is added. Isoconazole nitrate is used for the treatment of superficial fungal skin conditions. It has a broad spectrum of antifungal activity. It acts on dermatophytes as well as on yeasts and molds (including the causative agent of pityriasis versicolor). It also acts on the causative agent of erythrasma and on Gram-positive bacteria (such as Staphylococcus aureus, Staphylococcus / Micrococcus species, Streptococcus faecalis, Corynebacterium species (aerobic). Isoconazole nitrate does not result in selection of resistant organisms.

5.2 Pharmacokinetic properties: The isoconazole passes quickly from the cream into the skin. Maximum concentrations of active substance are reached within one hour in all skin layers. Isoconazole is not inactivated by metabolism in the skin. The systemic burden resulting from percutaneous absorption is low. The active substance which reaches the body through the skin is completely metabolized and eliminated rapidly 1/3 by the kidney and 2/3 in the bile. 0.1% Diflucortolone valerate is one of potent corticosteroids (class II). It stops inflammation in inflammatory skin conditions and alleviates subjective symptoms such as itching, burning or pain. It does not act against the underlying fungal infection. Diflucortolone valerate also passes quickly from the cream into the skin. Maximum concentrations in the stratum corneum were measured after 1 hour. Diflucortolone valerate undergoes only low hydrolyzation in the skin, so that the active substance rebsorbed in the skin is fully active locally. After an exposure of 4 hours, less than 1% of the amount of corticosteroid from the cream is resorbed. In the body, diflucortolone valerate is rapidly split into diflucortolone and valeric acid. The valeric acid is incorporated in the fatty acid metabolism; 75% of diflucortolone is eliminated by renal excretion and 25% in the bile, with a half-life of approximately 4 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 Shelf life: 3 years.

6.2 Special precautions for storage: Store at a temperature not exceeding 30°C.

6.3 SPECIAL PRECAUTIONS FOR ELIMINATION AND HANDLING: Duoskin® may leave oily stains on clothes; they can however be washed easily. The excipient is low in fat and cream is easily removed with water.

MA Holder: Dafra Pharma GmbH, Switzerland

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Dafra PHARMA

Duoskin®

isoconazole nitrate & diflucortolone valerate

EUROPEAN GMP

POWERFUL DOUBLE ACTION

Broad spectrum antifungal and anti-inflammatory agent

Proven antibacterial activity

The combination boosts the antifungal effect

Treatment of superficial mycosis
with highly inflammatory or eczematous
cutaneous manifestations.

For information about our other products, please visit www.dafrapharma.com and create your personal account.

SCAN

Dafra PHARMA

Setting the standard

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Duoskin®

isoconazole nitrate & diflucortolone valerate

POWERFUL DOUBLE ACTION

BROAD SPECTRUM ANTIFUNGAL AND ANTI-INFLAMMATORY AGENT

INDICATIONS

Duoskin® is the appropriate initial treatment for superficial fungal diseases of the skin, characterized by highly inflammatory or eczematous cutaneous phenomena, for example in the interdigital web spaces of the feet and hands, inguinal and genital area:

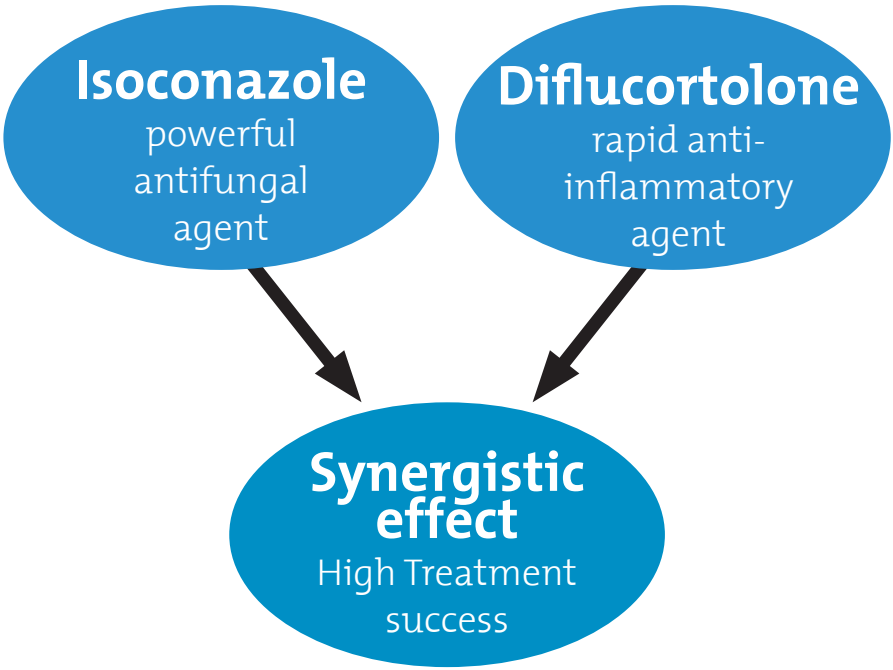
- Duoskin® works by reducing inflammation, redness and itching caused by dermatophytes
- Duoskin® helps to quickly eradicate the organisms involved
- Duoskin® is produced according to the strictest European GMP standards

DOSAGE

A thin layer of Duoskin® is generally applied 2 times a day on the affected cutaneous areas, with a light massage. In case of infection in spaces between the fingers and toes, it is often recommended to apply coated gauze of Duoskin® between the fingers or the toes.

DURATION OF TREATMENT

The treatment with Duoskin® should be stopped when the symptoms of skin inflammation or eczema improve, but not later than after 2 weeks, and followed, if necessary, by a cream that does not contain corticosteroids. This is especially true for application in inguinal and genital areas.



INCREASED BIOAVAILABILITY

PROLONGED ANTIMYCOTIC ACTIVITY

RAPID DECREASE IN INFLAMMATORY SYMPTOMS

REDUCTION IN THE RISK OF RE-INFECTION

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