

## **IZOCONAZOL-M 25g**

**Pharmaceutical form:** Cream 1%.

**Composition:** 1 g cream contains active substance – isoconazole nitrate 10 mg.

Inactive ingredients: Polysorbat 60, Sorbitan Stearate, Cetostearyl alcohol, Liquid paraffin, White soft paraffin, Purified water.

**Pharmacological group:** Used in the topical treatment of fungal infection.

### **Pharmacodynamic properties:**

Synthetic derivative of imidazole.

It has a local antifungal and antibacterial effect. It acts fungistatically, turned to be fungicidal with increasing the concentration. Active against dermatophytes *Trichophyton*, *Microsporum*, *Epidermophyton*, molds, yeasts *Candida*, and yeast-like fungi *Malassezia furfur* (*Pityrosporum* spp.), as well as erythrasma pathogen *Corynebacterium minutissimum* and gram-positive bacterias *Staphylococcus*, *Streptococcus*.

The mechanism of action of isoconazole is similar to the other antifungal spectrum drugs from group of imidazole derivatives, it inhibits the synthesis of ergosterol and changes the composition of the microbial cell membrane, which provides fungistatic and fungicidal effects of the drug.

### **Pharmacokinetic properties:**

Isoconazole penetrates rapidly into human skin from cream and reaches maximum drug concentrations in the horny layer and in the living skin 1 hour after application. High concentrations were maintained for at least 7 hours (horny layer: approx. 3500 µg/ml corresponding to 7 mmol/l, living epidermis approx. 20 µg/ml (40 µmol/l), dermis approx.

3 µg/ml (6 µmol/l). Removal of the horny layer prior to the application increased isoconazole concentrations in the living skin approximately by a factor of 2. Drug concentrations in the horny layer and the epidermis exceeded minimum inhibitory and biocidal antimycotic concentrations (MIC) of most important pathogens (dermatophytes, molds and yeasts) several fold and reached (MIC) values in the dermis. Isoconazole is not metabolically inactivated in the skin. Systemic load due to percutaneous absorption is low. Even after removal of the horny layer from 1 to 5% of the applied dose has reached the systemic circulation. Isoconazole nitrate is completely metabolized and rapidly eliminated. In a further study, isoconazole nitrate could still be detected above the MIC in the stratum corneum and the hair follicles at one week after termination of a two-week application period. In some subjects, isoconazole nitrate could even be detected 14 days after the last application.

### **Indications:**

Superficial fungal infections of the skin:

dermatomycosis of smooth skin, including with localization in the interdigital spaces and area of the external genital organs;

candidiasis of the skin;

pityriasis versicolor;

erythrasma

**Contraindications:**

Hypersensitivity to any of the components of the drug.

**Posology and method of administration:**

Cutaneous use. Izoconazol-M cream should be applied once daily to the affected areas of skin.

A general rule for fungal infections is that topical therapy be continued for a period of 2 to 3 weeks, and for 4 weeks in refractory infections (particularly infections of the interdigital spaces).

Longer period of treatment are also possible. To avoid recurrence, treatment should be continued for at least another 1-2 weeks after clinical healing.

**Undesirable effects:**

When using the drug, local reactions may occur, such as irritation, burning, and itching.

In rare cases, it is possible to develop allergic reactions at the site of the application of the drug.

**Precautions and Warnings:**

Izoconazol-M should not be allowed to come into contact with the eyes when being applied to the face. To prevent re-infection, it is recommended to change and boil personal linen daily (towels, underwear - preferably made of cotton). The physician should advise the patients on hygienic measures and skin care, if applicable, during the treatment. Care must be taken to dry thoroughly between the toes after each time washing, change socks and tights daily. In the treatment of fungus between the fingers, it is advisable to use bandages or tampons with Izoconazol-M cream. If Izoconazol-M cream is applied to the genital region, the excipients liquid paraffin and soft paraffin may cause damage of latex products for barrier methods such as condoms and diaphragms used concomitantly, thus impairing their effectiveness.

**Pregnancy and Lactation:**

During pregnancy, the use of Izoconazol-M cream is possible only under the supervision of a physician.

**Package:**

25 g in Alu tube with screw cap. Tube and leaflet insert in a paperboard box.

**Shelf life:**

5 years.

**Storage:**

Store below 30 °C. Keep out of reach of children.

**Legal status:**

Prescription only.