

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

OLY[®] 1% Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

1 g of OLY[®] contains 10 mg (1%) of isoconazole nitrate.

Excipients:

Cetostearyl alcohol 50 mg

Disodium EDTA 1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.

White to off-white cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For superficial fungal infections of the skin (e.g. in the region of the hands, the interdigital spaces of the feet and in the inguinal and genital regions) and additionally for Erythrasma.

4.2 Posology and method of administration

Posology/frequency and duration of administration:

OLY[®] Plus is applied once daily to the diseased areas of the skin.

Treatment lasts two to three weeks, four weeks for persistent infections (especially for interdigital infections), and longer treatment times are also possible.

To avoid relapses, OLY[®] should be used for at least two more weeks following clinical recovery.

Method of administration:

OLY[®] is applied externally to the diseased areas of the skin.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

OLY[®] should not be allowed to come into contact with the eyes when being applied to the face.

To prevent recurrent infections, personal clothing (cotton products should be preferred as hand and face cloths, towels, underwear, etc.) should be changed and boiled every day.

In the case of interdigital infection, it is recommended to place an OLY[®] applied gauze between the fingers or toes.

Regular hygiene measures are essential for the success of treatment with OLY[®]. In the presence of tinea pedis, after the feet are washed, the fingers should be well dried and the socks should be changed every day.

OLY[®] contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

OLY[®] contains sodium. However, it does not require any warning because of the method of use.

4.5 Interaction with other medicinal products and other forms of interaction

There is no known interaction.

4.6 Fertility, pregnancy and lactation

General recommendation

Pregnancy category is C.

Women with childbearing potential / Contraception

There are no data from the use of isoconazole nitrate/diflucortolon valerate in pregnant women.

Pregnancy

Data on the use of isoconazole-containing products during pregnancy indicate no teratogenic risk in humans.

Lactation

Effective quantities of isoconazole are unlikely to be secreted in breast milk.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed in patients treated with OLY[®].

4.8 Undesirable effects

Local symptoms such as itching, burning, erythema or vesicle formation occurred in a few isolated cases under treatment with isoconazole, the active ingredient of OLY[®] 1% cream.

Allergic skin reactions may also occur.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to Turkish Pharmacovigilance Center (TUFAM) (www.titck.gov.tr e-mail: tufam@titck.gov.tr; tel: 0 800 314 00 08; fax: 0 312 218 35 99).

4.9 Overdose

Drug substance isoconazole can actually be considered non-toxic according to the results from single-dose toxicity studies. Any risk of acute intoxication is to be expected following a single dermal application of an overdose (application over a large area increasing the absorption) or inadvertent oral ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topically used antifungals, imidazole derivatives.

ATC Code: D01AC05

Isoconazole nitrate is a drug developed for the treatment of superficial fungal diseases of the skin. It displays a very broad spectrum of antimicrobial action. It is effective against dermatophytes and yeasts, yeast-like fungi (including the causative organism of pityriasis versicolor) and molds, as well against gram-positive bacteria *in-vitro* and against the causative organism of erythrasma.

5.2 Pharmacokinetic properties

General properties

Absorption

Isoconazole, drug substance of OLY[®], penetrates rapidly into human skin. Systemic load due to percutaneous absorption is low. Even after removal of the horny layer less than 1 % of the applied dose has reached the systemic circulation within 4 hours exposure time.

Distribution

The peak active ingredient concentrations in the skin were reached after just 1 hour and persisted for at least 7 hours (stratum corneum: approx. 3,500 µg/ml ± 7 mmol/l, living epidermis: approx. 20 µg/ml ± 40 µmol/l, dermis: approx. 3 µg/ml ± 6 µmol/l). The active ingredient concentrations in the stratum corneum and the epidermis exceeded the minimum inhibitory concentration and the biocidal antimycotic concentration for the main disease pathogens (dermatophytes, moulds and yeasts) several times over and achieved these levels in the dermis.

Biotransformation

Isoconazole is not metabolically inactivated in the skin. 0.5 mg 3H-labelled isoconazole nitrate was administered by intravenous injection. Isoconazole was broken down completely and eliminated rapidly. 2,4-Dichloromandelic acid and 2-(2,6-dichlorobenzyloxy)-2-(2,4-dichlorophenyl)-acetic acid were characterized as quantitatively most important metabolites.

Elimination

A third of the labelled substances was excreted with the urine and two thirds with the bile; 75% of the total dose was already excreted within 24 hours.

Pharmacokinetic/pharmacodynamics relations

Removal of the horny layer prior to the application increased isoconazole concentrations in the living skin approximately by a factor of 2.

5.3 Preclinical safety data

The results of repeated dose toxicity studies yielded no evidence of specific health risks which might be associated with the use of isoconazole.

In vitro and in vivo studies to detect gene and chromosome mutations yielded no evidence of mutagenic potential associated with isoconazole. No in vivo carcinogenicity studies have been conducted. On the basis of current knowledge, no evidence of isoconazole-related tumorigenic potential can be derived from the results of mutagenicity testing, repeated dose toxicity studies or from the chemical structure and biochemical mechanism of action of the substance.

In a series of special reproduction toxicity studies, isoconazole exhibited no adverse effects on the individual phases of the reproductive cycle. Above all, there was no evidence of teratogenic potential.

According to the results of local tolerability studies on the skin and mucous membranes, no significant local irritation is to be expected under therapeutic conditions. Based on the results of studies in the rabbit eye, conjunctival irritation is to be expected following accidental contamination of the eye.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, liquid
Paraffin, white soft
Tween 60
Cetostearyl alcohol
Disodium EDTA
Sorbitan stearate
Deionized water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at room temperature below 25°C.

6.5 Nature and contents of container

Aluminum tube with 30 g sealed with plastic cap, placed in a box.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused medicinal product or waste material should be disposed of in accordance with the “Regulation on Medical Waste” and “Regulation on the Control of Packaging and Packaging Waste”.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

2015/952

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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