

Travocort®

Bayer Schering Pharma

This is a medicament

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- ▶ The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- ▶ Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers Union of Arab Pharmacists

▶ Composition

Isoconazole nitrate 1% and diflucortolone valerate 0.1%.

Excipients: polyethylene glycol sorbitan stearate, sorbitan stearate, cetyl stearic alcohol, white vaseline, liquid paraffin, sodium edetate and purified water.

Pharmaceutical form and contents

Cream, tube containing 20 g.

Pharmacotherapeutic group Topical antifungal.

► Manufacturer

Intendis Manufacturing S.p.A., Italy a division of

Bayer Schering Pharma AG, Germany

► Therapeutic indications

Superficial mycoses of smooth or hair-covered skin (dermatophytes, candidiasis, pityriasis versicolor). Because of the presence of diflucortolone valerate, Travocort is particularly indicated for the treatment of mycoses with skin manifestations that are markedly inflammatory or eczematous in character.

Contraindications

Hypersensitivity to one or more components. Presence in the area to be treated of tuberculous, luetic or viral lesions (vaccinia pustules, smallpox, varicella, herpes simplex).

▶ Precautions for use

In pregnant women and early infancy, the product is used only when absolutely necessary and under direct medical supervision.

Prolonged use of the product can promote the development of microorganisms not sensitive to the chemotherapeutic agent present in this preparation.

In this event, suitable therapeutic measures must be adopted.

In the case of application to the face, avoid contact of the preparation with the eyes.

 Interactions with other drugs or other kinds of interaction

None reported.

▶ Special warnings

Use of products for topical use, particularly if prolonged, can give rise to sensitisation phenomena. In this case, the treatment should be interrupted and suitable therapy should be instituted.

Dose and method of administration

Except when prescribed otherwise, the dosage of Travocort is 2 applications daily. In the case of interdigital lesions, it is often advisable to insert a gauze dressing soaked in Travocort between the toes. Following remission of the inflammatory and eczematous skin manifestations or after 1 week at the most, it is advisable not to continue application of Travocort but to continue is necessary with a simple antifungal agent or with the corticosteroid only.

▶ Undesirable effects

In the course of treatment of extensive areas of the body (about 10% or more of the total skin surface area) and with prolonged use (more than 4 weeks), as with other topical preparations with a corticosteroid base. it is not possible to rule out the occurrence of side effects due to absorption of the corticosteroid. Skin atrophy, hypertrichosis, hypopigmentation, striae, telangiectasias, burning sensation, irritation and folliculitis can be found locally.

The occurrence during the treatment of any undesirable effect not described in this information leaflet should be reported promptly to the treating doctor or pharmacist. Caution: do not use the medicine after the expiry date stated on the packaging.

Store below 30°C.

▶ Date of approval by the Ministry of Health March 2005