

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

TRAVOCORT 1%+0.1% cream

Isoconazole nitrate and
Diflucortolone valerate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again. - If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. You should not give the drug to others. It can harm them, even when their symptoms of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What's in this leaflet:

1. What is Travocort cream and what it is used for
2. What you need to know before using Travocort cream
3. How to use Travocort cream
4. Possible side effects
5. How to store Travocort cream
6. Contents of the pack and other information

1. What Travocort cream is and what it is used for

Travocort cream contains two active substances, isoconazole nitrate and diflucortolone valerate. Isoconazole nitrate belongs to a class of drugs called antifungals, and it treats fungal infections of the skin. Diflucortolone valerate belongs to a class of medicines called corticosteroids (cortisone) and suppresses skin inflammation to soothe discomforts such as itching, burning and pain.

Travocort cream is used for initial or intermediate treatment of superficial fungal skin infections accompanied by severe inflammation (redness, swelling, pain) or eczema, e.g. in the areas of the hands, interdigital footrests and groin and genitals.

2. What you need to know before using Travocort cream Do not

use Travocort cream:

- if you are allergic (hypersensitive) to isoconazole nitrate or diflucortolone valerate or any of the other ingredients of this medicine (listed in section 6).

- If you have skin conditions from tuberculosis or syphilis in the area where you will apply the cream.
- if you suffer from viruses e.g. herpes simplex, shingles or chickenpox.
- if you suffer from chronic inflammation of the skin of the face (rosacea), inflammation of the skin around the mouth (perioral dermatitis), common acne, wounds, dull ulcers or skin reactions after vaccination at the application site.
- in burns, because topical corticosteroids interfere with their healing and should not be used.

Warnings and precautions

Talk to your doctor or pharmacist before using Travocort cream.

When using Travocort cream it is important to know the following:

- If you also have a bacterial skin infection, your doctor will prescribe another medicine in addition to Travocort cream to treat this infection.
- When applying a tight bandage (e.g. diapers, bandages), you must clean the skin to avoid possible contamination.
- Regular hygiene measures are necessary for successful treatment with Travocort cream. To avoid cross-contamination, you must:
 - always wash your hands before and after using Travocort cream
 - The white clothes you use (facades, towels, underwear, etc. – cotton as much as possible) should be changed daily and washed with hot water, in order to avoid possible contamination
 - In mycosis of the feet the interdigital space should be dried well, □ In mycosis of the feet the socks should be changed daily.
- Do not use Travocort cream (because it contains corticosteroid) for more than two weeks without being reviewed by a dermatologist.
- Application of topical glucocorticosteroids to large areas of the body or for a prolonged period of time, especially with coating (eg bandage diapers), significantly increases the risk of side effects.
- When applying to the face, take special care as the skin on the face is particularly sensitive and local side effects are more likely to occur or skin changes caused by corticosteroid preparations may be observed
- Travocort cream may cause cataracts (clouding of the lens in the eye) and glaucoma (increased pressure inside the eye) when used in large doses or for a prolonged period of time, coated or in the area near the eyes. If used on the face, be careful that the drug does not come into contact with the eyes.
- Contact your doctor if you have blurred vision or other visual disturbances.
- If Travocort cream is applied to the genital area, its components liquid paraffin and soft paraffin can damage latex products such as condoms and diaphragms. For this reason, they can no longer be effective as methods of contraception or as protection against sexually transmitted diseases, such as HIV infection. Talk to your doctor or pharmacist if you need more information.
- After repeated application, at least 10-15 days, a temporary decrease or loss of corticosteroid activity (tachyphylaxis) may be observed. This phenomenon is restored after stopping use for a few days or weeks.
- In psoriasis, topical corticosteroids should be administered with caution and under the supervision of a specialist, because in addition to the temporary benefit, in the long term and after stopping treatment there is a risk of exacerbation of the disease.
- Due to adverse reactions from possible absorption, caution should be exercised when applied to large skin surfaces or for prolonged administration, especially in children, pregnant women, patients with severe kidney diseases, with bleeding diathesis and in upcoming vaccinations.

- In general, the least potent corticosteroid considered effective should be selected initially, and if there is no response, another of the same potency or greater strength should be administered.

Children and adolescents

Avoid long-term use in children. Children are more prone to systemic side effects from topical corticosteroid use because they may absorb larger amounts of medication due to a larger skin area relative to body weight.

Due to adverse reactions from possible absorption, caution should be exercised when applied to large skin surfaces or in prolonged administration, especially in children.

Travocort cream is recommended to be used in the paediatric population only if imperative with particular caution and under immediate medical supervision.

Other medicines and cream Travocort

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

No data are available on use in pregnant and lactating women. Therefore, if you are pregnant or breastfeeding, it is not recommended to use Travocort cream. *Pregnancy*

Do not use Travocort cream during the first three months of pregnancy. In later stages of pregnancy, your doctor will decide whether the expected benefit of using Travocort cream justifies the potential risk to the fetus. When the doctor deems it necessary to use Travocort cream during the second and third trimesters of pregnancy, use should be done with caution and under immediate medical supervision, and should not be applied for long periods of time to extensive areas of skin (more than 10% of body surface) and/or with occlusive dressing (bandages, etc.).

Breastfeeding

It is not known whether the active ingredients of Travocort cream pass into breast milk. Other glucocorticosteroids are excreted in breast milk. The risk to the breastfed child cannot be excluded. Therefore, you should not use Travocort cream during breastfeeding. Your doctor will carefully weigh the expected benefit of using Travocort cream. When the doctor deems it necessary to use corticosteroids during breastfeeding, you should stop breastfeeding. Avoid contact of the baby with the areas of skin where Travocort cream is applied.

Fertility

There is no evidence to suggest that fertility is affected by the use of Travocort cream.

Driving and using machines

No effects on the ability to drive and use machines have been observed in patients treated with Travocort cream.

However, if you experience visual disturbances, you should not drive and/or use machines and should contact your doctor.

Travocort cream contains ketostearyl alcohol

Travocort cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Travocort cream

Always use it strictly as your doctor or pharmacist has told you. If you are not sure, ask your doctor or pharmacist.

Unless otherwise recommended by the doctor, the usual recommended dose is: Apply twice daily to the affected area of skin.

- Stop using Travocort cream when the affected area of skin has improved.
- In general, the duration of treatment should not exceed two weeks.
- If necessary, your doctor may then prescribe treatment with an antifungal preparation that does not contain glucocorticoids. This is mainly recommended for the groin and genital area.
- Regular hygiene measures are necessary for successful treatment with Travocort cream (see section 2. What you need to know before using Travocort cream - Warnings and precautions).

Talk to your doctor or pharmacist if you think the effect of Travocort is too strong or too weak.

Use in children and adolescents

The use of Travocort cream in the paediatric population is recommended only if it is imperative, with particular care and under the direct supervision of the doctor (see section 2. What you need to know before using Travocort cream - Children and adolescents). No dose adjustment is necessary when children aged 2 years or older and adolescents are treated with Travocort.

Only limited data on the safety of Travocort cream in children below 2 years of age are available.

If you use more Travocort cream than you should

If you apply too much Travocort cream at once or accidentally swallow Travocort cream, this is not expected to be dangerous. However, contact your doctor or the nearest hospital immediately.

If you forget to use Travocort cream

Do not use a double dose to make up for a forgotten dose. When you remember, simply use the next dose and continue with treatment as prescribed.

If you stop using Travocort cream

Do not stop treatment abruptly without first contacting your doctor, as symptoms may recur.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following adverse reactions have been observed in clinical studies and are recorded according to their frequency:

Common (may affect more than 1 in 100 people and less than 1 in 10 people):

- skin irritation or burning sensation at the application site *Uncommon (may affect up to 1 in 100 people):*

- redness (erythema) or dryness at the application site
- stretch marks (skin streaks)

Frequency not known (frequency cannot be estimated from the available data): itching (itching) or blisters at the application site blurred vision

As with other glucocorticoids applied to the skin, the following local side effects can also occur with Travocort cream (their frequency cannot be estimated from the available data): thinning of the skin (skin atrophy), inflammation of hair follicles (folliculitis), growth of body hair (hirsutism), expansion of small superficial blood vessels in the skin (telangiectasia), inflammation of the skin around the mouth (perioral dermatitis), changes in skin colour, acne and/or allergic skin reactions to any of the ingredients of Travocort cream.

Since the components of Travocort cream are absorbed by the body through the skin, further side effects on other parts of the body (systemic effects) may occur.

Adverse reactions cannot be excluded in neonates whose mothers have treated extensive areas of skin or for a prolonged period of time during pregnancy or breastfeeding. For example, the activity of the baby's adrenal glands may decrease (decreased function of the adrenal cortex), and thus the baby's resistance to disease may decrease.

Local side effects following long-term topical use of corticosteroids Adverse reactions reported with topical corticosteroids at their sites are:

Burning sensation, itching, irritation, dryness, folliculitis, hypopigmentation, thinning of the skin, telangiectasias.

Modification of the clinical picture on incorrect use (mycoses, scabies). Secondary infection, local microbial infections (onset of latent infection or worsening progressive), fungal infections, facilitating the onset of molluscum contagiosum and condylomas acuminata.

Inhibition of wound healing, acne elements, pustules, summer sweat, perioral dermatitis, rash in the form of rosacea, recurrence of pustular psoriasis upon discontinuation of treatment (Rebound Phenomenon), skin atrophy in the form of scar, linear streaks, spider veins, purple rashes, diffuse erythema, papular vesicular atypical rashes, allergic hypersensitivity, local hirsutism, skin discoloration.

If symptoms of hypersensitivity occur, administration should be stopped immediately. The above side effects are not common, but may occur more frequently with the use of a watertight dressing or after long-term topical use.

General side effects after long-term topical use of corticosteroids

Suppression of the function of the cortico-adrenal axis, a drop in the level of cortisol in plasma – Cushing's syndrome.

Report side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects using ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal By reporting side effects you can help gather more information about the safety of this medicine.

5. How to store Travocort cream

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date is the last day of the month stated therein.

This drug does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Travocort cream contains

- The active substances are: isoconazole nitrate and diflucortolone valerate.
Each g of Travocort cream contains 10 mg (1%) isoconazole nitrate and 1 mg (0.1%) diflucortolone valerate.
- The other ingredients are: cetostearyl alcohol, Disodium edetate dihydrate, liquid paraffin, white soft paraffin, polysorbate 60, sorbitan stearate, purified water.

Appearance of Travocort cream and contents of the package

White to yellowish, opaque cream. Tube of 30g.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder in Greece and Cyprus

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