Package Leaflet: Information for the user

Travocort® 0.1 + 1 % w/w Cream

Diflucortolone valerate
Isoconazole nitrate

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Travocort® is and what it is used for
2. What you need to know before you use Travocort®
3. How to use Travocort®
4. Possible side effects
5. How to store Travocort®
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1. What Travocort® is and what it is used for

This medicine is used to treat fungal infections of the skin where inflammation (redness, swelling, soreness) is also a problem.
This medicine contains two active substances, isoconazole nitrate and diflucortolone valerate. Isoconazole nitrate treats fungal diseases of the skin and diflucortolone valerate suppresses inflammation of the skin and soothes complaints such as itching, burning and pain.

2. What you need to know before you use Travocort®

Do not use Travocort if you:

- are allergic (hypersensitive) to isoconazole nitrate or diflucortolone-valerate or any of the other ingredients of this medicine (listed in section 6),
- have skin lesions in the area to be treated which are associated with a tuberculosis or syphilis infection,
- have a viral infection e.g. herpes, shingles or chicken-pox (varicella, herpes zoster),
- have a chronic skin inflammation of the face (rosacea), skin inflammation around the mouth (perioral dermatitis) or a skin reaction following vaccination in the area to be treated.

Warnings and precautions

- **Talk to your doctor, pharmacist or nurse before using Travocort. When using Travocort it is important to know the following:** If you also have a bacterial infection of the skin, your doctor will prescribe you another medicine to use in addition to Travocort, to treat this infection.
- Do not allow Travocort to come into contact with the eyes when applying it to your face. Extensive application of glucocorticoid-containing topical medicines to large areas of the body or for prolonged periods of time, in particular under occlusion (e.g. diapers, dressings) increases the risk of side effects.
- There is a risk of developing an eye condition called glaucoma if you apply Travocort covered by a dressing, in large amounts, over a long period of time or if Travocort is applied to the area around the eyes.
- If Travocort is applied to the genital areas, some of its ingredients may cause damage to latex products such as condoms or diaphragms. Therefore, these may no longer be effective as contraception or as protection against sexually transmitted diseases such as HIV infection. Talk to your doctor or pharmacist, if you require more information.
- Regular hygienic measures are essential for successful Travocort treatment: To avoid renewed infection, you should
  - change your personal linen (face cloths, underwear etc. preferably of cotton) daily and boil them,
  - dry the area between the toes thoroughly after washing,
  - change your socks and stockings daily.

If symptoms do not improve, consult the doctor again.

Contact your doctor if you experience blurred vision or other visual disturbances.

Other medicines and Travocort

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Interactions of Travocort with other medicines are not known so far.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Your doctor will carefully weigh the benefits against the risks connected with the use of Travocort.
Glucocorticoids should not be applied during the first three months of pregnancy to avoid any risk to the development of the unborn baby.
If you are pregnant, you should in particular avoid applying Travocort covered by a dressing, to large areas of the body or using the cream for a longer time period.
It is not known whether the active ingredients of Travocort pass into breast milk. A risk to the suckling child cannot be excluded.

If you are breast-feeding you should

- not apply Travocort to the breasts;
- avoid applying Travocort covered by a dressing or to large areas of the body;
- avoid using Travocort for a longer time period.

There are no data showing that fertility is affected by the use of Travocort.

Driving and using machines:

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

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

3. How to use Travocort®

Always use Travocort exactly as your doctor or pharmacist has told you. You should check with them if you are not sure.
Do not use Travocort for more than 2 weeks.
Always wash your hands before and after applying Travocort.
Travocort should be applied twice daily to the diseased areas of skin. Stop using Travocort when the skin conditions have improved. In general, the duration of treatment must not exceed 2 weeks. If necessary, your doctor may then prescribe a follow-up treatment with a glucocorticoid-free anti-fungal preparation. This applies in particular if Travocort is applied to the groin or the genital area.

Regular hygienic measures are essential for successful Travocort treatment (see section 2 “Warnings and precautions”).

Use in children and adolescents
There is no need to adjust the dose when children aged 2 years or older and adolescents are treated with Travocort. Only limited data on the safety of Travocort in children aged below 2 years are available.

If you use more Travocort than you should
If you apply too much Travocort once, or accidentally swallow Travocort this is unlikely to be dangerous but contact your doctor or pharmacist if you are worried.

If you forget to use Travocort
Do not use a double dose to make up for a forgotten dose. When you remember, use the next dose and continue with the treatment as prescribed. See your doctor or pharmacist, if you are worried.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, Travocort can cause side effects, although not everybody gets them.
The following side effects occurred in clinical studies, they are listed according to their frequency:
Common: may affect up to 1 in 10 people
- skin irritation or burning feeling at the application site

Uncommon: may affect up to 1 in 100 people
- redness (erythema) or dryness at the application site
- stretch marks (skin striae)

Not known: frequency cannot be estimated from the available data
- itching (pruritus) or blisters (vesicles) at the application site
- blurred vision

As with other glucocorticoids that are applied to the skin, such as Travocort, the following local side effects may also occur (their frequency cannot be estimated from the available data):
Thinning of the skin (skin atrophy), inflammation of hair follicles (folliculitis), increased body hair growth (hypertrichosis), expansion of small superficial blood vessels in the skin (telangiectasia), skin inflammation around the mouth (perioral dermatitis), changes in skin color, acne, and/or allergic skin reactions to any of the ingredients of Travocort. Since the ingredients of Travocort are absorbed by the body through the skin, further side effects to other parts of the body (systemic effects) may occur.
Side effects cannot be excluded in newborns whose mothers have been treated extensively or for a prolonged period of time during pregnancy or while breast-feeding. For example, the activity of the baby’s adrenal glands may be reduced (reduced adrenocortical function) and so the baby’s resistance to disease may be lowered.

Reporting of 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 directly via:

Ireland
HPRA Pharmacovigilance
Earlsfort Terrace
IRL – Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Travocort®

Store Travocort out of the sight and reach of children.
Do not store above 30°C.
Do not use this medicine after the expiry date which is stated on the tube and carton after ‘EXP’. The expiry date refers to the last day of that month. Do not throw away any medicine 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 diflucortolone valerate and isoconazole nitrate. Travocort contains 0.1% w/w diflucortolone valerate (1mg/g) and 1% w/w isoconazole nitrate (10mg/g).
The other ingredients are:
Paraffin, white soft
Paraffin, liquid
Cetostearyl alcohol
Polysorbate 60
Sorbitan stearate
Disodium edetate dihydrate
Water, purified

See end of Section 2 for cetostearyl alcohol advice.

What Travocort looks like and contents of the pack
Travocort Cream is a white to yellowish opaque cream supplied in tubes of 15 g.

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LEO Pharma A/S
Industriparken 55, DK-2750 Ballerup
Denmark

Manufacturer:
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