SCHEDULING STATUS

S4

TRAVOCORT, 10 mg / 1 mg, cream

Isoconazole nitrate / diflucortolone valerate

Read all of this leaflet carefully before you start using TRAVOCORT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TRAVOCORT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TRAVOCORT is and what it is used for

1 g TRAVOCORT contains isoconazole nitrate 10 mg and 1 mg diflucortolone valerate in an easy to remove low fat base emulsion.

The active substances in TRAVOCORT are isoconazole nitrate and diflucortolone valerate. Other excipients include:
White soft paraffin, liquid paraffin, cetostearyl alcohol, polysorbate 60, sorbitan stearate, disodium edetate dihydrate, purified water.

TRAVOCORT is an anti-fungal medicine (an antimycotic) and an anti-inflammatory medicine (a corticosteroid) formulated as a cream to be used on the skin.
One of TRAVOCORT's active ingredients, isoconazole nitrate, is effective against dermatophytes and yeasts, yeast-like fungi (including the causative organism of pityriasis versicolor) and moulds, as well as against the causative organism of erythrasma. The other active ingredient, diflucortolone valerate, suppresses inflammatory and allergic skin reactions. TRAVOCORT is used for the initial or interim treatment of those superficial fungal infections of the skin which are accompanied by

highly inflammatory or eczematous skin conditions, e.g., in the region of the hands, the interdigital spaces of the feet, and in the groin and genital regions.

2. What you need to know before you use TRAVOCORT

Do not use TRAVOCORT:

- If you are hypersensitive (allergic) to isoconazole nitrate or diflucortolone valerate or any of the other ingredients of TRAVOCORT (listed in section 6).
- If you are suffering from TB (tuberculosis), or syphilis in the area to be treated, from virus diseases (for example: chicken pox/varicella, herpes zoster), from rosacea, perioral dermatitis, or post-vaccination skin reactions in the area to be treated.
- If you are pregnant.

Warnings and precautions

If you are taking other medicines on a regular basis; please consult your doctor, pharmacist or other health care professional for advice as using this medicine at the same time with other medicines may cause undesirable interactions.

If your doctor diagnoses that your skin disease is accompanied by bacterial infections, additional specific therapy is required.

If you apply TRAVOCORT to the face it should not be allowed to come into contact with your eyes.

If you have already suffered a previous case of glaucoma, be sure to inform your doctor.

Extensive application of topical corticosteroids to large areas of the body or for prolonged periods of time, in particular under occlusion, significantly increases the risk of side effects.

Glaucoma may develop from using topical corticosteroids such as TRAVOCORT (for example, after large-dosed or extensive application over a prolonged period, occlusive dressing techniques, or application to the skin around the eyes).

In infections of the spaces between toes or fingers, it is advisable to place a strip of gauze smeared with TRAVOCORT between the toes or fingers.

To avoid renewed infection, you should change your personal linen daily (washcloth, towel, underwear - preferably all of cotton) and these should be washed in very hot or even boiling water.

Regular personal hygiene is essential for successful TRAVOCORT treatment. In athlete's foot (*tinea pedis*), the space between your toes must be thoroughly dried after washing, and stockings or socks should be changed daily.

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you exeprinece a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Children

No data are available

Other medicines and TRAVOCORT

Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You should not use TRAVOCORT if you are pregnant, as there is limited information available on the safe use during pregnancy.

You should not use TRAVOCORT if you are breastfeeding your child, as there is limited information available on the safe use during breastfeeding.
You should also not be treated with TRAVOCORT on your breast, as your child may swallow some cream, which may be harmful.

TRAVOCORT should not interfere with your fertility or ability to have a child.

Driving and using machines

It is safe to use TRAVOCORT whilst driving or operating machinery.
It is not always possible to predict to what extent TRAVOCORT may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which TRAVOCORT affects you.

3. How to use TRAVOCORT

Do not share medicines prescribed for you with any other person.
Always use TRAVOCORT exactly as your doctor, or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is, unless otherwise prescribed by the doctor, for you to apply TRAVOCORT twice daily to the affected areas of skin.

Your doctor will tell you how long your treatment with TRAVOCORT will last.
In co-ordination with your doctor, the treatment with TRAVOCORT must be stopped after the inflammatory or eczematous skin condition has gone away.
If you have the impression that the effect of TRAVOCORT is too
strong or too weak, tell your doctor or pharmacist.

If you use more TRAVOCORT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take a dose of TRAVOCORT

Do not use increased amounts of TRAVOCORT CREAM to make up for a dose that you left out.

If you stop using TRAVOCORT

You should always consult your doctor before deciding to interrupt the course of treatment or stop using TRAVOCORT altogether.

4. Possible side effects

TRAVOCORT can have side effects.

Not all side effects reported for TRAVOCORT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TRAVOCORT, please consult your health care provider for advice.
If any of these side effects continue, are severe or bother you, tell your doctor or pharmacist.

In isolated cases under treatment with TRAVOCORT, symptoms such as itching, burning, redness (erythema), or blistering (vesiculation) in the area of the skin ailment may occur.

Tell your doctor if you notice any of the following:
Frequent side effects:

- application site irritation,
- application site burning.

Less frequent side effects:

- application site dryness,
- application site erythema,
- stretch marks.

Side effects with an unknown frequency:

- blurred vision,
- itching at the application site,
- blisters at the application site.
- If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

The following reactions may occur when TRAVOCORT is applied to large areas of the body (about 10 % and more) or for prolonged periods of time (more than 4 weeks): thinning of the skin (atrophy), swollen red skin, stretch marks, acneform changes of the skin, and systemic effects of the corticosteroid due to absorption.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA"s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of TRAVOCORT.

5. How to store TRAVOCORT

Store all medicines out of reach of children.

Store at or below 25 °C

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TRAVOCORT contains

The active substances are isoconazole nitrite and diflucortolone.

The other ingredients are cetostearyl alcohol, disodium edetate, liquid paraffin, Paraffin (white soft), Polysorbate 60, sorbitan stearate, water purified.

What TRAVOCORT looks like and contents of the pack

White to slightly yellowish opaque cream.

Tubes of 15 or 20 g made of aluminium with a high-density polyethylene HD-PE white screw cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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