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

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
6. Contents of the pack and other information

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)
are 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
(roacea), 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
textile products such as condoms or diapers.
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 hygiene 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.

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.

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

- Uncommon: may affect up to 1 in 100 people
  - itching (pruritus) or blisters (vesicles) at the application site

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 (hirsutism), 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 adrenal cortex function) and so the baby's resistance to disease may be lowered.

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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Bayer