**Patient Information Leaflet**

DUOSKIN**®**

Cream

Isoconazole nitrate 10 mg / Diflucortolone valerate 1 mg per g cream

**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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

1. **What is DUOSKIN® and what it is used for**

DUOSKIN® contains two active substances, isoconazole nitrate and diflucortolone valerate. Isoconazole nitrate treats fungal diseases of the skin and diflucortolone valerate is a corticosteroid which suppresses inflammation of the skin and soothes complaints such as itching, burning and pain (ATC code: D01AC20).

DUOSKIN® is used in the treatment of fungal infections of the skin where inflammation (redness, swelling, soreness) is also a problem.

1. **What you need to know before you use DUOSKIN® cream**

***Do not use DUOSKIN®***

* if you are allergic (hypersensitive) against any ingredient of the preparation (see section 6),
* if you have tuberculosis,
* if you have skin lesions in the area of treatment which are associated with syphilis,
* during the application of live virus vaccine,
* if you have a chronic skin inflammation of the face (rosacea) or around the mouth.

***Warnings and precautions***

***Talk to your doctor before using DUOSKIN®***

* DUOSKIN® should never be applied into the eye.
* Treatment should be stopped in case of chemical irritation and hypersensitivity reaction.
* Extensive application of DUOSKIN® 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. Children are more sensitive to the active ingredients.
* If DUOSKIN® 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 lo longer be effective as contraception or as protection against sexually transmitted diseases such as HIV infection.
* If symptoms do not improve, consult the doctor again.

***Other medicines and DUOSKIN®***

* Tell your doctor if you are taking, have recently taken or might take other medicines, including medicines obtained without a prescription.
* Interactions of DUOSKIN® with other medicines are not known so far.

***Pregnancy, breast-feeding and fertility***

* DUOSKIN® is used during pregnancy only if expected benefit outweighs the possible risks. 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.
* DUOSKIN® diffuses into maternal milk, thus should not be used in nursing mothers.

1. **How to use DUOSKIN®**

**Always take it exactly as your doctor or pharmacist has told you.**

* Duoskin® is for external use only.
* Duoskin® should be applied once or twice daily to cover the diseased areas of skin.
* Always wash your hands before and after applying DUOSKIN®.
* Stop using DUOSKIN® when the skin conditions have improved. In general, the duration of treatment must not exceed 2 weeks.
* Regular hygienic measures are essential for successful DUOSKIN® treatment.

**If you apply more DUOSKIN® than you should,** or accidentally swallow DUOSKIN®, this is unlikely to be dangerous but contact your doctor or pharmacist.

**If you forget to use DUOSKIN®,** do not use a double dose to make up for a forgotten dose.

**Possible side effects**

The following side effects have been reported:

Common (1/10):

* Skin irritation or burning feeling at the application site.

Uncommon (1/100):

* Redness or dryness at the application site.
* Stretch marks.

Not known:

* Itching or blisters at the application site.

As with other glucocorticoids that are applied to the skin, such as DUOSKIN®, the following local side effects may also occur:

* Thinning of the skin.
* Inflammation of hair follicles.
* Increased body hair growth.
* Expansion of small superficial blood vessels in the skin.
* Skin inflammation around the mouth.
* Changes in skin color.
* Acne.
* Allergic skin reactions to any of the ingredients of DUOSKIN®.
* 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.

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

1. **How to store DUOSKIN®:** Store below 30°C, in the original package. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging (Exp.). The expiry date refers to the last day of that month.
2. **Other information**

**What DUOSKIN® contains:** Active Substance: each gram cream 10 mg Isoconazole nitrate and 1 mg Diflucortolone valerate.List of excipients: Liquid paraffin, Polysorbate 60, Disodium edetate, White soft parafine, Cetostearyl alcohol, Sorbitan stearate, purified water.

**DUOSKIN®** is a white cream, presented in a 15 g tube.

**DUOSKIN®** is a prescription only medicine.

Manufacturer: BILIM PHARMACEUTICALS GOSB 41480 Gebze-Kocaeli, Turkey.

Registration/Licence Holder: Dafra Pharma GmbH, Mühlenberg 7, 4052 Basel, Switzerland.

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