

PATIENT INFORMATION LEAFLET

OLY[®] Plus cream

External use.

Active substance: 1 g of OLY[®] Plus contains 10 mg (1%) of isoconazole nitrate and 10 mg (0.1%) of diflucortolone valerate.

Excipients: Liquid paraffin, white soft paraffin, polysorbate 60, cetostearyl alcohol, disodium EDTA, sorbitan stearate and deionized water.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet because you may need to read it again.*
- *If you have any further questions or are not sure about anything, please ask your doctor or your pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others as it may harm them, even if their symptoms are the same as yours.*
- *Tell your doctor or pharmacist that you use this medicine if you visit your doctor or go to the hospital.*
- *Strictly follow these instructions. Do not take **lower or higher doses** than the recommended dose.*

What is in this leaflet:

- 1. What OLY[®] Plus is and what it is used for?**
- 2. What you need to know before you use OLY[®] Plus**
- 3. How to use OLY[®] Plus?**
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1. What OLY[®] Plus cream is and what it is used for?

OLY[®] Plus is used for initial or interim treatment of 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 inguinal and genital regions).

OLY[®] Plus is a white, opaque cream available in 15 g aluminum tubes.

Isoconazole nitrate is for use in the treatment of superficial fungal diseases of the skin. It is effective against many microbes; it is effective against dermatophytes and yeasts, yeast-like fungi (including the causative organism of pityriasis versicolor) and molds, as well against the causative organism of erythrasma, which is an infectious skin disease manifesting with red, brown spots.

Diflucortolone valerate prevents inflammation in inflammatory and allergic skin conditions and alleviates the complaints such itching, burning and pain.

2. What you need to know before you use OLY[®] Plus Cream

Do not use OLY[®] Plus Cream

If;

- you are allergic to the active ingredients isoconazole nitrate, diflucortolone valerate or any of the other ingredients of OLY[®] Plus.
- you have tuberculosis or syphilis; viral infection (e.g. 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.

Take special care with OLY[®] Plus

If;

- you have a bacterial infection of the skin, an appropriate adjuvant therapy is required
- used on the face, OLY[®] Plus should not be allowed to come into contact with the eyes.
- you have had glaucoma before, inform your doctor.
- you take drugs that contain miconazole, econazole and thioconazole inform you doctor.

Extensive application of topical glucocorticoids to large areas of the body or for prolonged periods of time, in particular under occlusion, may increase the risk of systemic side effects.

Caution should be exercised when being applied to the face, groin and armpits and used in children due to the increased risk of side effects. The increase in systemic absorption in children should also be considered.

As known from systemic glucocorticoids, glaucoma may also develop from using local glucocorticoids (e.g. after large dosed or extensive application over a prolonged period, occlusive dressing techniques, or application to the skin around the eyes).

It is often advisable to place a strip of gauze smeared with OLY[®] Plus between the toes or fingers if these areas are affected.

To prevent recurrent infections, personal clothing (cotton products should be preferred as hand and face cloths, towels, underwear, etc.) should be changed and boil-washed every day.

Regular hygiene measures are essential for the success of treatment with OLY[®] Plus. In case of fungal infections of the feet (known as tinea pedis), after the feet are washed, the fingers should be well dried and the socks should be changed every day.

Please consult your doctor if these warnings apply to you even at any time in the past.

Taking OLY[®] Plus with food and drinks

You can use OLY[®] Plus while you eat and drink.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor that you are pregnant or you may be pregnant because your doctor will want to take this into account before prescribing OLY[®] Plus.

As a general rule, the use of externally applied preparations containing corticosteroids in the first trimester of pregnancy is inconvenient. You should in particular avoid applying to large areas of the body and using the cream for a longer time period.

Breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine.

If you are breastfeeding a toddler or an infant, you should not apply OLY[®] Plus to your breasts. Tell your doctor that you are breastfeeding because your doctor will want to take this into account before prescribing OLY[®] Plus. You should in particular avoid applying to large areas of the body and using the cream for a longer time period.

Driving and using machines:

OLY[®] Plus has no known effect on driving and use of machines.

Important information on some excipients present in OLY[®] Plus

If you are not allergic to the excipients contained in OLY[®] Plus, an adverse reaction to these excipients is not expected.

OLY[®] Plus contains cetyl stearyl alcohol that can cause local skin reactions (e.g. contact dermatitis).

OLY[®] Plus contains sodium. However, it does not require any warning because of the method of use.

Taking other medicines

If you are taking or have recently taken any other medicines, including medicines without a prescription, tell your doctor or pharmacist.

3. HOW TO USE OLY[®] Plus

Instructions for proper use and dosage/administration frequency:

Always use OLY[®] Plus exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

OLY[®] Plus is applied twice daily.

Stop using OLY[®] Plus when the inflammatory or eczematous skin conditions have improved, no later than 2 weeks. If necessary, your doctor may then prescribe a follow-up treatment with a corticosteroid-free cream. This applies in particular when the cream is applied to the groin or the genital area.

Route and method of administration:

OLY[®] Plus is externally applied to the infected areas of the skin.

Different age groups:

In children: It should be used with caution in children because of the increased risk of systemic absorption and side effects.

Special conditions of use:**Renal/Hepatic Failure:**

The reversible hypothalamic pituitary adrenal (HPA) axis suppression occurs following systemic absorption associated with the prolonged use of high-potency topical corticosteroids on large surface areas, under occlusion, or in patients with concomitant hepatic insufficiency

If you have the impression that the effect of OLY[®] is too strong or weak, talk with your doctor or pharmacist.

If you use more OLY[®] Plus than you should

If you use more OLY[®] Plus than was prescribed, do not worry, tell your doctor or pharmacist.

An overdose for once (one time application to a large area of the skin) or accidental indigestion is unlikely to cause any risk.

If you forget to use OLY[®] Plus

Your doctor will decide when you will use the missed dose. It is important that you follow the instructions of your doctor for the next application.

Do not take double dose to make up the dose you have missed.

Effects that may occur if you stop taking OLY[®] Plus

If you use OLY[®] Plus as recommended by your doctor, symptoms will disappear during treatment and complete recovery will be achieved after treatment. If the symptoms continue or arise again, contact your doctor.

4. Possible Side Effects

Like all medicines, OLY[®] Plus can cause side effects, although not everybody gets them.

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

Application of topical preparations containing corticosteroids over a large area (10% or more of the body surface) or for a prolonged time (4 weeks or longer) may result in the following side effects: thinning of the skin (skin atrophy), expansion of small superficial blood vessels in the skin (telangiectasia), striae, acne-like changes and systemic effects due to corticosteroid resorption.

Immune system disorders:

Rare: Allergic contact dermatitis

Skin and subcutaneous disorders:

Rare: Local symptoms such as inflammation of hair follicles (folliculitis), increased body hair growth (hypertrichosis), skin inflammation around the mouth (perioral dermatitis), changes in skin color, rash, itching, burning, Redness (erythema) or the formation of inflamed vesicles on the skin (vesicularisation), irritation, dryness, softening of the skin (maceration), rash.

These are mild and usually transient side effects resulting from the use of topical corticosteroids; complaints disappeared after the treatment. Following topical treatment, approximately 1% of patients may experience local effects such as itching or burning.

Local irritation and burning occurred in 0.5% to 4% of patients receiving topical treatment with diflucortolone valerate.

When OLY[®] Plus is administered over a prolonged or extended period during pregnancy or lactation, it is possible that some side effects may occur in newborns (eg reduction in adrenal function in the last weeks of pregnancy).

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to Turkish Pharmacovigilance Center (TUFAM) (www.titck.gov.tr e-mail: tufam@titck.gov.tr; tel: 0 800 314 00 08; fax: 0 312 218 35 99).

5. How To Store OLY[®] Plus

Store OLY[®] Plus in its original packaging and keep out of the reach and sight of children.

Store at room temperature, below 30°C.

Use in compliance with the expiry date.

Do not use OLY[®] Plus after the expiry date which is stated on the packaging.

Marketing Authorization Holder:

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This leaflet has been approved on .././.....