PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine can be sold under doctor's prescription only

Triderm® Cream

Composition:
Each gram contains:
Betamethasone dipropionate 0.643* mg
*Equivalent to 0.5 mg Betamethasone.
Clotrimazole 10.00 mg
Gentamicin (as sulfate) 1.00 mg

For a list of inactive ingredients, see section 6 "FURTHER INFORMATION". See also section 2.5 "Important information about some of the ingredients of **Triderm Cream**".

Read all of this leaflet carefully before you start using the medicine.
- This leaflet contains concise information about **Triderm Cream**. If you have any further questions, refer to the doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their medical condition seems similar to yours.

1. WHAT TRIDERM CREAM IS USED FOR?

Triderm Cream is indicated for the treatment of dermatoses responsive to corticosteroids when complicated by secondary infections caused by bacteria (sensitive to gentamicin) and fungi (sensitive to clotrimazole) or when the possibility of such infections is suspected.
The cream is suitable for the treatment of oozing eczema.

Therapeutic Group:
Betamethasone - potent glucocorticoid.
Clotrimazole - antifungal.
Gentamicin - aminoglycoside antibiotic.

2. BEFORE USING TRIDERM CREAM

2.1 Do not use Triderm Cream

- if you are sensitive (allergic) to betamethasone dipropionate, clotrimazole, gentamicin sulfate or any of the other ingredients of this medicine. For a list of inactive ingredients, see section 6.
- in cases of skin infections [of viral, bacterial (including tuberculosis) and fungal aetiology] or syphilitic skin diseases, chicken pox (varicella), herpes infections (e.g. fever blisters), vaccine reactions, skin ulcers and acne. The doctor should be informed immediately.
- facial application is not recommended in the presence of rosacea or perioral dermatitis.
- in case of open wounds or damaged skin areas.
- under occlusive dressings.
- do not use on mucous membranes, to the eyes or the area around the eyes.

2.2 Special warnings regarding use of Triderm Cream

Triderm Cream is a very effective pharmaceutical product. Do not use **Triderm Cream** longer than the prescribed time period. Normally the treatment duration for adults and adolescents is maximum 2-3 weeks otherwise the skin may get damaged.

If your skin disease does not respond to the treatment within a few days or is even getting worse, contact your doctor. Please inform your doctor if itching, redness, blisters, a marked thinning or lesions of the skin occur.

If your symptoms recur shortly after the end of treatment within 2 weeks, do not use the cream without first consulting a doctor again, unless your doctor has instructed you to do so. If your symptoms recur after they have subsided, you should seek medical advice before repeating the treatment if the redness extends beyond the area originally treated and the skin burns.

If unexpected hypersensitivity reactions occur, in form of redness or swelling of the skin area, the treatment must be discontinued.

It should be avoided to treat extensive body areas (more than 10% of the body surface) or highly absorbing skin areas [open wounds, damaged skin, intertriginous areas (skin folds), bends of the joints, between fingers and toes, the muco-cutaneous junction and around the eyes].

If **Triderm Cream** is used on extensive skin areas or for long-term, skin changes may occur; impact on the skin thickness, dilatation and increase of blood vessels, formation of stripes and spots. Therefore do not use **Triderm Cream** on extensive skin areas without consulting your doctor.

Tell your doctor if blurred vision or visual disturbances occur. Your doctor will decide whether or not to consult an ophthalmologist to determine what are the possible causes (including opacity of the lens, glaucoma or other rare diseases) of your visual disturbances.

Triderm Cream should be used with caution in children from the age of 2-12 years, not longer than 5-7 days and not on extensive body areas. The use in children under the age of 2 years is not recommended.

If **Triderm Cream** must be used in children from the age of 2-12 years, the treatment should be closely monitored by a doctor, as the active substances may penetrate the skin and cause undesirable events. This applies in particular for the treatment of highly absorbing skin areas like the face, neck, scalp, genital or rectal region and in skin folds.

When **Triderm Cream** is used in the genital or anal region, the presence of the excipients petroleum jelly and liquid paraffin may diminish the tear resistance of concomitantly used latex condoms, thereby compromising their safety when in use.

2.3 Pregnancy, breastfeeding and fertility

If you are pregnant or want to become pregnant or if you are breast feeding, you should only use **Triderm Cream** after consulting your doctor.

2.4 Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, you should inform the attending doctor or pharmacist.

2.5 Important information about some of the ingredients of Triderm Cream
Triderm Cream contains cetosteayl alcohol which may cause a local skin reactions (e.g. contact dermatitis).
Triderm Cream contains propylene glycol 100 mg in each gram of the cream. Propylene glycol may cause skin irritation.
Since **Triderm Cream** contains propylene glycol, it should not be applied to areas of skin with open wounds or extensive skin damage (e.g. burns).
Triderm Cream contains benzyl alcohol 10 mg in each gram of the cream. Benzyl alcohol may cause allergic reactions or mild local irritation.

3. HOW SHOULD YOU USE TRIDERM CREAM?
Always use **Triderm Cream** as instructed by the doctor.
You should check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen.
The dosage and treatment regimen will be determined by the doctor only.

Unless otherwise directed by your doctor the recommended dosage is as follows:
Apply enough quantity of the cream to cover the entire affected area, usually in the morning and in the evening.
Do not use **Triderm Cream** for more than 3 weeks in infants and children under 4 years of age, especially on areas covered by diapers. Unless otherwise directed by the physician, do not use an occlusive dressing on the affected area (plastic diapers are considered occlusive dressings).
Do not exceed the recommended dose.

Attention:
Do not swallow! This medicine is intended for external use only.
Avoid contact with the eyes and mucous membranes (e.g. in mouth and nose), see section 2.2 ‘’Special warnings regarding use of **Triderm Cream**”.

If you have accidentally used more Triderm Cream than you should
If you have used an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you have further questions on the use of the medicine, consult with a doctor or a pharmacist.

4.SIDE EFFECTS
As with any medicine, **Triderm Cream** may cause side effects, in some users.
Do not be alarmed by reading the list of side effects, you may not suffer from any of them.

*The following side effects may occur when using **Triderm Cream**:*

Skin irritations, burning, itching, dryness and hypersensitivity and skin discoloration may occur. It is not known whether the skin discoloration is reversible.
After long-term application a thinning of the concerned skin areas, a dilatation of small superficial blood vessels and the formation of blue-reddish stripes may occur.

If used on extensive skin areas, occlusive dressings or if applied on damaged skin, the active substance may penetrate the skin and cause undesirable events. This includes endocrine disrupting effects or the occurrence of a so far (symptomless) latent diabetes.

Withdrawal reaction after end of treatment:
After continuous use for an extended period of time, a withdrawal reaction may occur after treatment ends. This may include one or more of the following symptoms: redness of the skin that may extend beyond the treated area, a burning or stinging sensation, severe itching, peeling skin, oozing open blisters.

Blurred vision has been reported with the use of topical corticosteroids.

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by using the link "Reporting side effects due to medicinal treatment" at the home page of the Ministry of Health's web site (www.health.gov.il) which refers to the online side effects reporting form, or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE TRIDERM CREAM?

- Avoid Poisoning! This medicine, and any other medicine must be stored in a safe place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of the indicated month.
- **Storage conditions**:
  Store below 25°C.
  After first opening, **Tridem Cream** can be used for 3 months.
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment**.**

6. FURTHER INFORMATION

In addition to the active ingredients **Triderm Cream** also contains:
White soft paraffin, propylene glycol, cetostearyl alcohol, liquid paraffin, cetomacrogol 1000, benzyl alcohol, sodium dihydrogen phosphate dihydrate, phosphoric acid, sodium hydroxide, purified water.

What **Triderm Cream** looks like:
Smooth, uniform, white to off-white cream, free from foreign matter.

Pack sizes:
15 gr or 30 gr tubes.
Not all pack sizes may be marketed.

License holder and address:
Organon Pharma Israel Ltd., 1 Atir Yeda, Kfar Saba

Manufacturer: Organon LLC, NJ USA

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Drug registration no. listed in the official Registry of the Ministry of Health:
105.13.28792