PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
This medicine is to be supplied upon physician'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 sulfate equivalent to 1.00 mg Gentamicin base

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 INTENDED FOR?

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

Triderm Cream is indicated for 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.

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 tuberculous or syphilitic skin diseases, chicken pox (varicella), herpes infections (e.g fever blisters) or vaccine reactions and acne. The doctor should be informed immediately.
- in case of open wounds or damaged skin areas.
- under occlusive dressings. Do not use on mucous membranes.
- in the area near the eyes.

2.2 Special warnings regarding use of Triderm Cream

Triderm Cream is a very effective pharmaceutical product. Do not exceed the duration of treatment prescribed by the doctor, which is normally a maximum of 2 to 3 weeks for adults and adolescents, as otherwise skin damage may occur.

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 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 it 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 you doctor.

2.4 Taking other medicines

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

2.5 Important information about some of the ingredients of Triderm Cream

Triderm Cream may cause a localised skin reaction (e.g. contact dermatitis) due to the presence of cetostearyl alcohol.
Triderm Cream contains propylene glycol 100 mg in each gram of the cream.
Triderm Cream may cause skin irritation due to the presence of propylene glycol.

Triderm Cream 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.
Do not exceed the recommended dose.

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).
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.

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 "Adverse Drug Reactions Report" 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 dehydrate, Phosphoric acid, Sodium hydroxide, Purified water

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

Pack size:
15 gr.

License holder:
Merck Sharp & Dohme (Israel-1996) Company Ltd., P.O.Box 7121, Petah-Tikva 49170.

Manufacturer:
Schering-Plough Labo N.V., Heist-Op-Den-Berg, Belgium.

Revised in June 2021 according to MOHs guidelines.

Drug registration no. listed in the official Registry of the Ministry of Health:
1051328792