

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

This medicine is to be supplied upon physician's prescription only

**DIPROGENTA®
CREAM**

Each gram of cream contains:
Betamethasone dipropionate 0.64 mg*
* Equivalent to 0.5 mg Betamethasone
Gentamicin (as Sulfate) 1 mg

**DIPROGENTA®
OINTMENT**

Each gram of ointment contains:
Betamethasone dipropionate 0.64 mg*
* Equivalent to 0.5 mg Betamethasone
Gentamicin (as Sulfate) 1 mg

For a list of the inactive ingredients see section 6 "FURTHER INFORMATION".

Read the entire leaflet carefully before you start using the medicine.

- This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or the 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 IS THE MEDICINE INTENDED FOR?

DIPROGENTA is used for the local treatment of inflammatory skin diseases with secondary infections caused by microorganisms sensitive to gentamicin.

The ointment can be used for lesions on dry skin, the cream on oily skin and for weeping conditions.

Therapeutic group:

DIPROGENTA is a combination product containing two active substances: betamethasone dipropionate and gentamycin. Betamethasone dipropionate is part of a drug group named topical corticosteroids (for local use). It is classified as a "effective corticosteroid" (powerful). Gentamycin is an antibiotic that belongs to the aminoglycoside group.

2. BEFORE USING THE MEDICINE

2.1 Do not use the medicine:

- if you are sensitive to betamethasone dipropionate, gentamicin sulfate or any other components of this medicine (for a list of inactive ingredients, see section 6).
- in case of tuberculous or skin diseases related to syphilis, herpes infections (e.g. fever blisters), chicken pox (varicella) or vaccine reactions.
- in case of acne
- on mucus tissues, in the eyes or the area near the eyes
- in case of open wounds or purulent inflammations, the doctor should be informed immediately.

2.2 Special warnings regarding use of the medicine

Do not use **DIPROGENTA** longer than the time period prescribed by the doctor. Normally the treatment duration for adults and adolescents is maximum 2-3 weeks; in case the treatment duration is longer, the skin may get damaged.

Before starting treatment with DIPROGENTA, tell your doctor:

- If you are suffering from other illnesses or have allergies.
- If unexpected hypersensitivity reactions occur, the treatment must be discontinued.
- If your skin disease does not respond to the treatment within a few days or is even getting worse, contact your doctor. The cause may be an allergy or an infection by insusceptible germs. Please inform your doctor if itching, redness, blisters or a marked thinning of the skin occurs.
- Diprogenta cream contains chlorocresol which may cause allergic reactions and cetostearyl alcohol which may cause localized skin reactions (e.g. contact dermatitis).
- 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 or toes, the muco-cutaneous junction and around the eyes].
- 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.
- **DIPROGENTA** 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 **DIPROGENTA** 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 through 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 **DIPROGENTA** 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 Taking other medicines

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

2.4 Pregnancy and breastfeeding

If you are pregnant, planning to be pregnant or breastfeeding, you should only use **DIPROGENTA** after consulting your doctor. Tell your doctor if you become pregnant prior or during treatment.

3. HOW SHOULD YOU USE DIPROGENTA?

Always use **DIPROGENTA** as instructed by the doctor. You should check with the doctor or the pharmacist if you are not sure regarding the dosage and method of treatment. The dosage and method of treatment will be determined by the doctor only.

The usually recommended dose is:

Adolescents and adults

If not prescribed otherwise, apply a sufficient amount twice daily on the affected skin areas and rub in gently to the skin.

In children from the age of 2-12 years apply a thin amount, not more than twice daily, with at least 6-12 hours between applications.

Do not change the dose by yourself. Talk to your doctor or to your pharmacist if you think that the effect of the medicinal product is too strong or too weak.

Do not exceed the recommended dose.

This medicine is intended for external use only.

If you have accidentally taken a higher dose

If you have taken 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.

If you have forgotten to use the medicine

If you forgot to use this medicine at the specific time, do not use a double dose. Use the next dose at the usual time and consult the doctor.

Treatment must be continued as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor.

How can you contribute to the success of the treatment?

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

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

4. SIDE EFFECTS

As with any medicine, **DIPROGENTA** 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 **DIPROGENTA**:

Skin irritations, burning, itching, acne, dryness, 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 appearance of diabetes symptoms in case of 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, you should 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](https://sideeffects.health.gov.il)

5. HOW TO STORE THE MEDICINE?

- 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) that appears on the packaging. The expiry date refers to the last day of the indicated month.
- **Storage conditions:** Store up to 25°C. After first opening, can be used up to 3 months.

- Medicines should not be disposed of via wastewater or household waste. Ask your 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 the medicine also contains:
DIPROGENTA Cream: white petrolatum, cetostearyl alcohol, mineral oil, , polyethylene glycol 1000 monocetyl ether, sodium phosphate monobasic, chlorocresol, phosphoric acid, purified water, sodium hydroxide or phosphoric acid for PH adjustment.
DIPROGENTA Ointment: Mineral oil, white petrolatum.
- **What the medicine looks like and the contents of the package**
DIPROGENTA Cream is a smooth, white, uniform cream, free from lumps and foreign matter.
DIPROGENTA Ointment is a smooth, uniform off-white ointment, free from foreign matter.

Pack sizes:

DIPROGENTA Cream is supplied in a tube of 15 g.

DIPROGENTA Ointment is supplied in a tube of 15 g.

License holder and address:

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 March 2021 according to MOHs guidelines.

Registration number of the medicine listed in the National Drug Registry of the Ministry of Health:

DIPROGENTA Cream: 134.32.24138

DIPROGENTA Ointment: 134.12.23893