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

This medicine can be sold under doctor'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''. See also section 2.5 "Important information about some of the ingredients of **DIPROGENTA**".

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 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 DIPROGENTA IS USED 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 gentamicin. Betamethasone dipropionate is part of a drug group named topical corticosteroids (for local use). It is classified as a "potent corticosteroid" (powerful). Gentamicin 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 (allergic) to betamethasone dipropionate, gentamicin sulfate or any other components of this medicine (for a list of inactive ingredients, see section 6).
- in case of skin infections [of viral, bacterial (including tuberculous) and fungal aetiology] or skin diseases related to syphilis, herpes infections (e.g. fever blisters), chicken pox (varicella) or vaccine reactions.
- Facial application is not recommended in the presence of rosacea or perioral dermatitis**.**
- in case of skin ulcers and acne.
- on mucus tissues, to the eyes or the area around 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

DIPROGENTA is a very effective pharmaceutical product. Do not use **DIPROGENTA** 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.

Before starting treatment with DIPROGENTA, tell your doctor:

- 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.
- If your symptoms recur shortly after the end of treatment, within 2 weeks, do not use **DIPROGENTA** 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.
- 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, you should inform the attending doctor or pharmacist.

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

2.5 Important information about some of the ingredients of DIPROGENTA
DIPROGENTA CREAM contains chlorocresol which may cause allergic reactions.
DIPROGENTA CREAM also contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

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 accidently used more DIPROGENTA than you should
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 without consulting your doctor.

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 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 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, 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

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 25ºC. 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: White petrolatum, mineral oil.
- **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 gram.
  DIPROGENTA Ointment is supplied in a tube of 15 gram.

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

Manufacturer: Organon LLC, NJ USA

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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