

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

The medicine is dispensed with a doctor's prescription only

BETACORTEN G Cream/Ointment

Active ingredients and their concentrations:

Betamethasone (as 17-valerate) 0.1%

Gentamicin (as sulphate) 0.1%

Inactive ingredients: see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have 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 it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Betacorten G is intended for the local treatment of inflammatory and allergic skin conditions accompanied by infection.

Therapeutic group:

Betamethasone - potent corticosteroid.

Gentamicin - antibiotic belonging to the aminoglycoside group.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are hypersensitive (allergic) to betamethasone valerate, gentamicin or to any of the other ingredients contained in Betacorten G (listed in section 6).
- in children under 1 year of age.
- do not use the preparation on mucosal tissues (anus, genitals, around the mouth/nose).
- to treat of any of the following skin problems, since the medicine may cause them to worsen:

- acne
- severe flushing of skin on and around the nose (rosacea).
- spotty red rash around the mouth.
- skin infections originated from a virus (e.g., shingles/herpes, chickenpox), fungus or tuberculosis of the skin.

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Betacorten G.

Special warnings regarding use of the medicine

Talk to your doctor or pharmacist before using the medicine if:

- you have previously had an allergic reaction to another steroid or to another antibiotic.
- you are suffering, or have suffered in the past, from impaired function of the liver, kidney or immune system.
- you are suffering, or have suffered in the past, from diabetes, glaucoma or cataract.
- you are using the preparation for a prolonged period or frequently.
- you have psoriasis - the doctor will want to see you more often.
- if you are suffering a chronic leg ulcer, as you may be at increased risk of a local allergic reaction.
- you are applying to an extensive skin area.
- you are applying the ointment/cream on broken skin, within the skin folds.
- you are applying to thin skin such as the face or on children, as their skin is thinner than that of adults and as a result, may absorb larger amounts.
- you are applying near the eyes or on the eyelids, as cataract or glaucoma may result if the ointment/cream repeatedly enters the eye.

- You are applying the ointment/cream under a airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. You may thereby accidentally end up using too much of the medicine.

- Do not use dressings or bandages on children or on the face where the ointment/cream is applied.

- Use on children or on the face must be limited to 5 days.

- Special caution is required when using in children and adolescents. Use at these ages must be accompanied by medical monitoring.

- If you are sensitive to any food or medicine, especially antibiotics, inform the doctor before using the medicine.

- Sometimes use of antibiotics for local treatment promotes growth of other microorganisms, including fungi. If you identified a fungal infection or if an irritation develops due to the use of the preparation which contains gentamicin, you should stop treatment with this medicine and replace it with another appropriate treatment.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, if you are taking ritonavir, itraconazole or if you are using other preparation(s) for external use.

Pregnancy, breastfeeding and fertility

Do not use the medicine without consulting the doctor before starting the treatment if you are pregnant or breastfeeding, think you may be pregnant, or are planning to become pregnant.

Important information about some of the ingredients in the medicine

Betacorten G Cream contains chlorocresol, which may cause allergic reactions, and cetostearyl alcohol, which may cause local skin reactions (e.g., contact dermatitis).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is:

- Apply Betacorten G once or twice a day. This dosage may be reduced as the skin begins to get better.
- This ointment/cream is for use on your skin only.
- Do not use more than the amount prescribed for you and do not exceed the recommended frequency and duration of treatment.
- Do not apply on skin of the face for a period exceeding 5 days, unless indicated otherwise by the doctor.
- Do not use on extensive areas of the body for a long time (e.g., every day for many weeks or months), without instruction from the doctor.
- The bacteria that cause infections like warm and moist conditions under bandages or dressings; therefore, always clean the skin before putting on a fresh dressing.
- If you are applying the ointment/cream on someone else, make sure you wash your hands after use or wear disposable plastic gloves.
- If the skin problem does not improve within one week, consult the doctor.
- The ointment is recommended for use on dry skin where penetration is difficult.
- The cream is recommended for use on wet weepy areas and on areas where convenient rinsing is desired.

Do not swallow.

For external use only.

Instructions for applying the ointment/cream

1. Wash your hands.

2. Apply a thin layer to the affected areas and rub gently until it has been fully absorbed into the skin.

3. Wash your hands again after using the ointment/cream unless you are meant to apply the ointment/cream to your hands as part of the treatment.

For children

- Do not use in children under 1 year of age.
- The duration of treatment in children should not exceed 5 days (particularly in areas covered with nappies), unless the doctor has told you to use the ointment/cream for longer.
- Parents must inform the attending doctor about any side effect, as well as any additional medicine being given to the child! See section 4 for a list of side effects.

If you have psoriasis

If you have thick lesions of psoriasis on the elbows or knees, the doctor may suggest applying the ointment/cream under an airtight dressing. The dressing should only be put on at night to help the ointment/cream start working. After a short period of time, apply the ointment/cream normally.

If you apply Betacorten G to the face

Apply the ointment/cream to the face only as per the doctor's instruction. Do not use for more than 5 days, since the skin of the face thins easily.

Do not allow the ointment/cream to enter the eyes. In case of contact with the eyes, wash them thoroughly with water.

Do not exceed the recommended dose. This is especially important when treating children.

If you accidentally took a higher dosage

If you applied too much or accidentally swallowed the ointment/cream, you may get sick. Refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

If you forgot to take this medicine

If you forgot to apply this medicine at the required time, apply it as soon as you remember. If it is close to the next time you meant to apply it, wait until that time.

Adhere to the treatment as recommended by the doctor.

If you stop taking the medicine

If you use Betacorten G regularly, speak with your doctor before you stop the treatment with the medicine. Your condition may worsen if the treatment is stopped suddenly.

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

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

4. SIDE EFFECTS

As with any medicine, use of Betacorten G may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue use and refer to a doctor immediately if:

- you find that your skin condition is getting worse, you develop a generalized rash or your skin becomes swollen during treatment. You may be allergic to Betacorten G or you need other treatment.
- you have psoriasis and you develop bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

Additional side effects:

- Common side effects** (may occur in up to 1 in 10 people)
- a feeling of heat, burning, pain, irritation or itching where the ointment/cream was applied.

These effects usually pass within a short time after the adaptation period to the preparation. However, if they do not pass or if there is some other change for the worse in the skin, stop the treatment and refer to the doctor.

Very rare side effects (may occur in up to 1 in 10,000 people) but are more common in children and infants:

- an increased risk of infection
- an allergic skin reaction where the ointment/cream is applied
- rash, irritated and bumpy skin or redness of the skin
- dryness and thinning of your skin; it may also damage or wrinkle more easily
- stretch marks may develop
- veins under the skin may become more noticeable
- an increase or reduction in hair growth or hair loss and changes in skin color
- weight gain, rounding of the face
- delayed weight gain or slowing of growth in children
- bones may become thin, weak and break easily
- cloudy lens in the eye (cataract) or increased pressure in the eye (glaucoma)
- increased blood sugar levels or sugar in the urine
- high blood pressure

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

Side effects can be reported to the Ministry of Health via the online side effects reporting form that can be found on the homepage of the Ministry of Health www.health.gov.il or through the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- Store in a cool place, at a temperature below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Betacorten G Cream:

Liquid Paraffin, Cetostearyl Alcohol, Macrogol Cetostearyl Ether, Chlorocresol, Sodium Acid Phosphate, Phosphoric Acid, Purified Water.

Betacorten G Ointment:

Liquid Paraffin, White Soft Paraffin.

What does the medicine look like and what are the contents of the package? The package contains a tube with 15 g white cream/ointment.

Manufacturer and registration holder: Trima, Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000.

This leaflet was checked and approved by the Ministry of Health in November 2015.

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

Betacorten G Cream: 050.42.23259.00

Betacorten G Ointment: 050.45.23262.00

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