

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

The medicine is dispensed according to a physician's prescription only

Betnovate Ointment

Betamethasone (as valerate) 0.1% w/w

Each 1 g contains 1 mg of betamethasone (as valerate).

For the list of the inactive and allergenic ingredients in the medicine, see section 6 – “Additional information”.

Read the 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 physician or pharmacist.

This medicine has been prescribed for the treatment of your ailment. 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?

Betnovate contains a medicine called betamethasone valerate.

Betamethasone valerate is a potent topical steroid indicated for adults, elderly and children over 1 year of age for the relief of inflammatory and pruritic manifestations of steroid responsive dermatoses including the following:

- Atopic dermatitis (including infantile atopic dermatitis)
- Nummular dermatitis (also called discoid eczema)
- Prurigo nodularis
- Psoriasis (excluding widespread plaque psoriasis)
- Lichen simplex chronicus (neurodermatitis) and lichen planus
- Seborrhoeic dermatitis
- Irritant or allergic contact dermatitis
- Discoid lupus erythematosus
- Adjunct to systemic steroid therapy in generalised erythroderma

Therapeutic group: Corticosteroids.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- If you are sensitive (allergic) to betamethasone valerate or to any of the additional ingredients contained in this medicine (as listed in section 6)
- For treatment of any of the following skin problems, as the medicine could make them worse:
 - acne
 - severe flushing of the skin on and around the nose (rosacea)
 - spotty red rash around the mouth
 - itching around your anus or genitals (penis or vagina)
 - skin infections from a viral, bacterial and fungal source (unless the infection is being concurrently treated with an anti-infective medicine)
 - itchy skin which is not inflamed

Do not use in children under 1 year of age.

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

Special warnings regarding use of the medicine

Before the treatment with Betnovate, tell the physician if:

- You have previously had an allergic reaction to another steroid.
- You are applying the ointment under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. Therefore, you may accidentally use too much medicine.
- You have psoriasis, the physician will want to see you more often.
- You are using the medicine for a chronic leg ulcer as you may be at increased risk of a local allergic reaction or infection.
- You are applying to a large skin surface.
- You are applying the ointment on broken skin or within the skin folds.
- You are applying near the eyes or on the eyelids, as cataracts or glaucoma may result if the ointment repeatedly enters the eye.

- You have a skin infection, as this will need to be treated.
- 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, greater amounts of Betnovate may be absorbed.
- Dressings or bandages should not be used on children or on the face where the ointment is applied.
- Use of Betnovate on the skin of children or on facial skin should be limited to 5 days.

If you are suffering from blurred vision or other visual disturbances, contact your physician.

If there is a worsening of your condition during use, consult your physician – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

Do not smoke or go near naked flames due to the risk of severe burns.

Fabric (clothing, bedding, dressing, etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

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

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the ointment/cream without consulting your physician unless your physician has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, seek medical advice before restarting treatment.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Especially if you are taking ritonavir and itraconazole medications.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician for advice before using this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

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

The recommended dosage is usually:

- Applying Betnovate once or twice a day. The dosage may be reduced as the condition of your skin begins to get better.
- This ointment is intended for use on your skin only.
- Do not use a dosage higher than that prescribed for you.
- Do not use on large areas of the body for a long time (such as every day for many weeks or months), without instruction from the physician.
- Germs that cause infections like warm and moist conditions that exist under bandages or dressings, therefore always clean the skin before a fresh dressing is applied.
- If you are applying the ointment on someone else, make sure you wash your hands after use or wear disposable plastic gloves.
- If your skin problem does not improve within 2 to 4 weeks, consult with the physician.

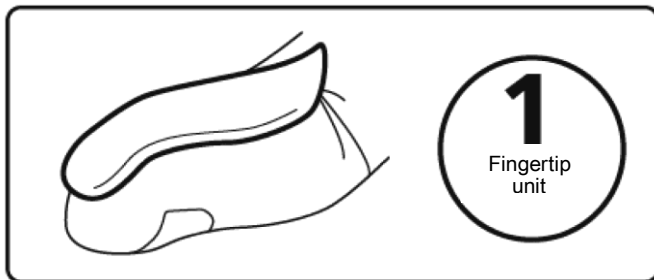
Do not swallow

For external use only

Guidance on how to apply the ointment

1. Wash your hands.
2. Apply a thin layer to the affected areas and gently rub until it all absorbs into the skin. You can measure how much Betnovate to use with your fingertip (as demonstrated in figure 1). For children, you will need to use

less ointment, but still use an adult finger to measure out the fingertip unit.



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

Use in adults

The diagram shows a simple line drawing of an adult human figure. Lines point from the text on the right to the corresponding body parts on the figure: the face and neck, the back, the front of the torso, one arm, both sides of one hand, one leg, and one foot.

Face and neck:
2½ fingertip units.

Back: 7 fingertip units.

Front:
7 fingertip units.

One arm (not including the hand):
3 fingertip units.

Both sides of one hand:
1 fingertip unit.

One leg (not including the foot):
6 fingertip units.

One foot:
2 fingertip units.

Do not worry if you find you need a little more or less ointment than described above. It is only a rough guide.

Use in children aged 1-10

Number of fingertip units needed					
Child's age	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
1-2 years	1½	1½	2	2	3

3-5 years	1½	2	3	3	3½
6-10 years	2	2½	4½	3½	5

- **Do not use on children under 1 year of age.**
- It is especially important in children not to exceed the recommended amount.
- A course of treatment for a child should not normally last for more than 5 days, unless the physician has told you to use the ointment for a longer period of time.

If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your physician may suggest applying the ointment under an airtight dressing. Only dress the area at night, to help the ointment start working. After a short period of time, apply the ointment as normal.

If you apply Betnovate to your face

You should only apply the ointment to the skin on your face if your physician tells you to. It should not be applied to your face for more than 5 days, as the skin on your face thins easily. **Do not allow the ointment to get into your eyes. Do not exceed the recommended dose. This is especially important when treating children.**

If you accidentally have taken a higher dosage

If you applied too much or if you or if a child have/has accidentally swallowed the ointment, it could make you or the child ill. Refer immediately to a physician or 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 scheduled time, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until that time.

Adhere to the treatment regimen recommended by your physician.

If you stop taking the medicine

If you use Betnovate regularly, talk to your physician before you stop using it. Your condition may get worse if the treatment is stopped suddenly.

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 further questions regarding use of the medicine, consult the physician or the pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Betnovate 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.

Discontinue use and refer immediately to the physician if:

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

Additional side effects you may notice when using Betnovate ointment include:

Common side effects

These may affect **up to 1 in 10** people:

- a feeling of burning, pain, irritation or itching where the ointment is applied.

Very rare side effects

These may affect **up to 1 in 10,000** people:

- an increased risk of infection
- an allergic skin reaction where the ointment is applied

- rash, itchy 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
- blood vessels under the surface of your 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 can become thin, weak and break easily
- cloudy eye lens (cataract) or increased pressure in the eye (glaucoma)
- a decrease in the level of the hormone cortisol in the blood
- increased blood sugar levels or sugar in the urine
- high blood pressure

Side effects of unknown frequency (frequency was not yet determined)

- blurred vision
- Steroid withdrawal reaction: If used continuously for a prolonged period, a withdrawal reaction may occur upon stopping treatment, with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a

closed 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 the physician.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 30°C.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:
White soft paraffin and liquid paraffin.
- What Betnovate ointment looks like and the contents of the package: Within each carton is a tube with a plastic screw cap and contains 15, 30 or 100 grams of ointment.
Not all package sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Operations (UK) Limited, Barnard Castle, UK.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 017-04-24760

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