

**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).

A list of the additional ingredients is detailed in section 6.

**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 ailment is similar.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

Betnovate contains a medicine called betamethasone valerate.

Betnovate is used to reduce the inflammation and itchiness of certain skin problems, such as eczema, psoriasis and dermatitis in adults and children over the age of one.

**Therapeutic group:** Corticosteroids.

### **2. BEFORE USING THE MEDICINE**

**Do not use the medicine:**

- If you are hypersensitive (allergic) to betamethasone valerate or to any of the additional ingredients contained in Betnovate (as listed in Section 6)
- In children under 1 year of age
- 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 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 the use of the medicine**

Before 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.

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.

#### **Other medicines and Betnovate**

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

#### **Pregnancy and breastfeeding**

If you are pregnant or are breastfeeding, think you may be pregnant or are planning to become pregnant, consult with your pharmacist or physician before taking this medicine.

### **3. HOW SHOULD YOU USE THE MEDICINE?**

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

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

The usual dosage is generally:

- 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 infection 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.

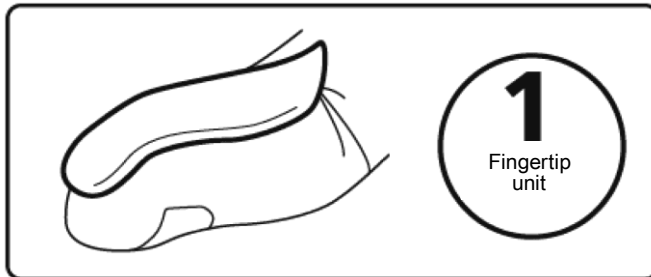
- If your skin problem does not improve within 2 to 4 weeks, consult with the physician.

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



<b>Face and neck:</b>	2½ fingertip units.
<b>Back:</b>	7 fingertip units.
<b>Front part of the body:</b>	7 fingertip units.
<b>One arm (not including the hand):</b>	3 fingertip units.
<b>Both sides of one hand:</b>	1 fingertip unit.
<b>One leg (not including the foot):</b>	6 fingertip units.
<b>One foot:</b>	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 part of the body	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 have accidentally 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 the 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 the 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 the 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 of the users. Do not be alarmed by reading the list of side effects. You may not experience 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:

**Common side effects** (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** (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**

- blurred vision

**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 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](http://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.

## 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 pack sizes may be marketed.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Glaxo Operations (UK) Limited, Barnard Castle, UK.
- Revised in March 2021 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 017-04-24760

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*Bet Oin PT v2A*