

**Patient leaflet in accordance with the
Pharmacists' Regulations (Preparations) - 1986**

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

Betnovate Scalp Application

betamethasone valerate 0.1% w/w

Each 10 ml contains 0.01 ml of betamethasone valerate

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

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 physician 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.

The medicine is not intended for children under 1 year of age.

1. What is the medicine intended for?

Betnovate Scalp Application (called 'Betnovate' in this leaflet) contains a medicine called betamethasone valerate.

Betnovate is used to help reduce the redness and itchiness of certain scalp problems, such as psoriasis and dermatitis associated with dandruff.

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 of Betnovate (as listed in Section 6)
- if you have a skin infection on your scalp (viral, bacterial and fungal)
- on children under 1 year of age.

Do not use Betnovate 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

Talk to your physician or pharmacist before you use this medicine if:

- you have previously had an allergic reaction to another steroid.
- you are applying the solution under an airtight dressing. These types of dressings make the absorption of the active ingredient through the skin easier and it is possible to accidentally end up using too high a dosage of the solution.
- you have psoriasis; your physician will want to see you more often.
- you are applying the solution to broken skin or within the skin folds.
- you are applying to a large surface area.
- you are applying to thin skin or on children as their skin is thinner than that

- of adults and, as a result, may absorb larger amounts of the solution.
- Dressings should not be used on children where the scalp application is applied.
 - Use on children should be limited to 5 days.

Contact your physician if you experience blurred vision or other visual disturbances.

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

Pregnancy, breastfeeding and fertility

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

3. How should you use the medicine?

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

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

The usual dosage is generally:

- Application of Betnovate on your scalp in the morning and at night. The dose may be reduced as your scalp problem begins to get better.
- Do not use Betnovate more often than prescribed for you.
- Do not use Betnovate for a long time (such as every day for many weeks or months) without a physician's instruction.
- Be very careful not to get the solution into your eyes. Do not touch your eyes until you have washed your hands.
- If you wash or shampoo your hair, wait until your hair dries before applying the solution.
- If you are applying Betnovate on someone else, make sure you wash your hands after use or wear disposable plastic gloves.
- **Do not dry your hair with a hairdryer.**
- **Caution! Inflammable substance; avoid exposure of the solution to an open fire, flames and any other source of ignition, including smoking when applying or immediately after applying the solution, until the preparation has fully dried.**

Guidance on how to apply the solution

- 1) Wash your hands.
- 2) Unscrew the bottle cap and place the nozzle on the scalp that needs treating.
- 3) Gently squeeze the bottle to cover the area with a thin and even layer of

solution.

- 4) You can rub the solution in, but you do not have to.
- 5) Your scalp will feel cool until the solution has dried.
- 6) Wash your hands again.

Do not exceed the recommended dosage

Do not swallow.

For external use only.

If you have accidentally taken a higher dosage

You might feel unwell if you have applied too much or if you or a child accidentally swallowed the medicine. Refer immediately to a physician or proceed 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 Betnovate, apply it as soon as you remember. If it is close to the time you are next meant to apply it, you can wait until this time.

Adhere to the treatment regimen as recommended to you by the physician.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the physician or pharmacist.

If you stop taking the medicine

If you use Betnovate regularly, talk to your physician before you stop using it. 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 a medicine. Wear glasses if you need them.

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

4. Side effects

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

Stop using Betnovate and refer immediately to the physician if:

- you find that your skin condition is getting worse, you develop a generalised 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 get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.

Additional side effects you may notice when using Betnovate include:

Common side effects (may occur in up to 1 in 10 people)

- a feeling of burning, pain, irritation or itching in the area where the solution is applied.

Very rare side effects (may occur in up to 1 in 10,000 people)

- an increased risk of infection
- an allergic skin reaction of area where solution is applied
- rash, itchy bumpy skin or redness of the skin
- dryness and thinning of your skin which may also damage or wrinkle more easily
- stretch marks may develop
- veins under 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 lens in the eye (cataract) or increased pressure in the eye (glaucoma)
- 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 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 should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe 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 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 25°C.
- Protect from light. Do not expose Betnovate Scalp Application to direct sunlight.
- Keep the container tightly closed when not in use. Contents are inflammable. Keep Betnovate Scalp Application away from all sources of fire, flame and heat.
- Use within 3 months after first opening, but not past the expiry date.

6. Further information

- In addition to the active ingredient, the medicine also contains: isopropyl alcohol, carbomer, sodium hydroxide, purified water
- What Betnovate looks like and the contents of the package:

Within each carton is a plastic bottle with a nozzle and cap that contains 30 ml or 100 ml of a sticky liquid.

Not all pack sizes may be marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.
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