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Package Leaflet: Information for the User



Betnovate Scalp Application

Betamethasone valerate

- Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
 - If you have any further questions, ask your doctor or pharmacist.
 - This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
 - If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Betnovate is and what it is used for
- 2 What you need to know before you use Betnovate
- 3 How to use Betnovate
- 4 Possible side effects
- 5 How to store Betnovate
- 6 Contents of the pack and other information

1 What Betnovate is and what it is used for

Betnovate Scalp Application (called 'Betnovate' in this leaflet) contains a medicine called betamethasone valerate. It belongs to a group of medicines called steroids that help to reduce swelling and irritation. Betnovate is used to help reduce the redness and itchiness of certain scalp problems, such as psoriasis and dermatitis.

2 What you need to know before you use Betnovate

Do not use Betnovate:

- if you are allergic (hypersensitive) to betamethasone valerate or any of the other ingredients of Betnovate (listed in Section 6)
- if you have a skin infection on your scalp
- on a child under 1 year.

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

Warnings and precautions

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

- you have previously had an allergic reaction with another steroid
- you are applying the liquid under an airtight dressing. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much
- you have psoriasis, your doctor will want to see you more often
- you are applying the liquid 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 adults and as a result may absorb larger amounts.
- Dressing or bandages should not be used on children where the scalp application is applied.
- Use on children should be limited to 5 days.

Contact your doctor 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 doctor or pharmacist before using this medicine.

Other medicines and Betnovate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

Pregnancy and breast-feeding and fertility

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

3 How to use Betnovate

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine

- You usually put Betnovate on your scalp in the morning and at night. This may be reduced as your scalp problem begins to get better.
- Do not use Betnovate more often than prescribed.
- Do not use it for a long time (such as every day for many weeks or months) - unless your doctor tells you to.
- Be very careful not to get the liquid in your eyes. Do not touch your eyes until you have washed your hands.
- If you wash or shampoo your hair it should be dried before applying the liquid.
- 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.**
- **This product is flammable. Keep the liquid away from open fires and flames and all sources of ignition including smoking during application and immediately after use.**

Guidance on how to apply the liquid

- 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 liquid.
- 4 You can rub this liquid in, but you don't have to.
- 5 Your scalp will feel cool until the liquid has dried.
- 6 Wash your hands again.
- 7 It is important not to exceed the prescribed amount.

If you use more Betnovate than you should

If you apply too much or if accidentally swallowed, it could make you ill. Talk to your doctor or go to the hospital as soon as possible.

If you forget to use Betnovate

If you forget 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.

If you stop using Betnovate

If you use Betnovate regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Betnovate and tell your doctor immediately if:

- you find that your skin condition gets 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.

Other side effects you may notice when using Betnovate include:

Common

(may affect up to 1 in 10 people)

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

Very rare

(may affect up to 1 in 10,000 people)

- an increased risk of infection
- an allergic skin reaction where the liquid is applied
- rash, itchy bumpy skin or redness of the skin
- thinning and dryness of your skin and it may also damage or wrinkle more easily
- stretch marks may develop
- veins under the surface of your skin may become more noticeable
- an increase or reduction in hair growth or hair loss and changes in skin colour
- 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 eye (glaucoma)
- increased blood sugar levels or sugar in the urine
- high blood pressure

Not Known

(frequency cannot be estimated from the available data)

- blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

To report Product Complaints or Adverse Event/s associated with the use of GSK product/s, please contact us via:

gulf.safety@gsk.com

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Betnovate

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the bottle label or carton after (EXP). The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Keep the container tightly closed when not in use. Contents are flammable. Keep Betnovate Scalp Application away from all sources of fire, flame and heat.
- Do not leave Betnovate Scalp Application in direct sunlight.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Betnovate contains

- The active ingredient is betamethasone valerate. Each 10 ml contains 0.01 ml of betamethasone (0.1 % w/w) as valerate.
- The other ingredients are:
 - Carbomer
 - Isopropyl alcohol,
 - Sodium hydroxide
 - Purified water.

What Betnovate looks like and contents of the pack

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

Manufactured by

Aspen Bad Oldesloe GmbH

Bad Oldesloe

Germany

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THIS IS A MEDICAMENT

Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists.

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GSK SDC is responsible for site technical requirements and pre-press suitability.

GSK Market is responsible to advise SDC when changes required impact the following:

Formulation
Tablet embossing
Storage conditions
Shelf Life

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Local approvers must ensure that trade mark and copyright statements included in the brief comply with guidance provided by Legal: Global Trade Marks.

ASPEN BAD OLDESLOE

Site Additional Artwork Information Panel

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