

Reason for update: HPRA PAC- ADDITION OF PROTECT FORM LIGHT & MOISTURE
STATEMENT

Market: Ireland

Agency Approval Date:

Text Date: 13/04/2022

Text Issue and Draft No.: Issue 6, Draft 2

Package leaflet: Information for the user

Betnovate Scalp Application 0.1% w/w Cutaneous Solution betamethasone (as 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.
- In this leaflet, Betnovate Scalp Application 0.1% w/w Cutaneous Solution will be called Betnovate.

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 contains the active substance betamethasone valerate which belongs to a group of medicines called corticosteroids that help to reduce redness, swelling and irritation of the skin. These should not be confused with “anabolic steroids” misused by some body builders and taken as tablets or injections.

Betnovate is used to help reduce the redness and itchiness of certain scalp problems, such as psoriasis (thickened patches of inflamed, red skin, often covered by silvery scales), an inflamed scalp due to severe dandruff, and dermatitis in adults and children over the age of 1 year.

Betnovate also contains an alcohol which has an antiseptic effect.

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 this medicine (listed in section 6).
- if you have a skin infection on your scalp.
- on a child under the age of 1 year.

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

Stop using Betnovate and tell your doctor as soon as possible if:

you find that you develop an allergic reaction, the area being treated becomes infected, or if you are being treated for psoriasis and you get raised bumps with pus under the skin (pustular psoriasis).

Warnings and precautions

Talk to your doctor or pharmacist before using Betnovate.

- If you are allergic (hypersensitive) to any corticosteroids.
- Only use Betnovate for as long as your doctor recommends.
- Only use an airtight dressing over this medicine if your doctor has told you to. If you are applying the liquid under an airtight dressing, make sure that the skin is cleansed before a fresh dressing is applied to prevent infections. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much.
- Prolonged use with occlusive dressings can cause the body to produce lower levels of the hormone cortisol than normal.
- If you have psoriasis, your doctor will want to see you more often.
- If you are using this for a prolonged period of time there is a possibility you may develop a cataract (clouding of the eye's lens).

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

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

Children

- Do not use this medicine on a child under the age of 1 year.
- Avoid continuous treatment for a long period of time in infants and children under the age of 12 years as adrenocortical suppression (where the body produces lower levels of the hormone cortisol than normal) and growth retardation may occur.

Other medicines and Betnovate

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may affect how Betnovate Scalp Application works or make it more likely that you'll have side effects. Examples of these medicines include:

- ritonavir and itraconazole

Tell your doctor or pharmacist if you are taking any of these. There are other medicines which may have a similar effect. It is therefore very important to **tell your doctor or pharmacist** if you're taking any other medicines, if you've taken any

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recently, or if you start taking a new one. This includes medicines bought without a prescription.

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 doctor or pharmacist for advice before taking this medicine.

You should not use this medicine if you are pregnant or breast-feeding unless your doctor has recommended you to do so.

If you do use Betnovate when breast-feeding, **do not use it on your breast area** to ensure that the **baby does not accidentally get Betnovate in their mouth.**

3 How to use Betnovate

Always use this medicine exactly as your doctor or pharmacist 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.
- For use on your skin of your scalp only.
- 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.
- This medicine should not be used every day for more than 4 weeks at a time.
- 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.
- If your scalp problem does not improve tell your doctor.
- Due to the flammable nature of Betnovate, you should avoid smoking or being near an open flame while you are applying it and immediately after you've used it.

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 As soon as the scalp problem looks better use once a day or less.

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Use in children

- Do not use this medicine on children under the age of 1 year.
- Avoid continuous treatment for a long period of time in infants and children under the age of 12 years.

If you use more Betnovate than you should

If, by mistake on a few occasions you use more than you should, do not worry.

If you continue to use too much over a period of time you may develop symptoms such as: stretch marks, the appearance of blood vessels under the surface of your skin, increased body hair, changes to the colour of your skin, skin thinning, weight gain, moon face/rounding of the face.

If any of these symptoms occur or you think you have used too much of this medicine talk to your doctor or go to hospital as soon as possible.

If you accidentally swallow Betnovate, it could make you ill. Rinse your mouth out with plenty of water and contact your doctor or pharmacist for advice.

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, wait until this time. Do not apply extra Betnovate to make up for missed doses.

If you stop using Betnovate

If you use Betnovate regularly make sure you talk to your doctor before you stop using it.

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 as soon as possible if:

- you find that your skin condition gets worse or becomes swollen during treatment. You may be allergic to the Betnovate, have an infection or need other treatment.
- you have psoriasis and you 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

- local skin burning or pain
- itchy skin

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Very rare: may affect up to 1 in 10,000 people

Use of Betnovate for a long period of time, or use under an airtight dressing, may cause the following symptoms:

- increased weight
- rounding of the face/moon face
- obesity
- thinning of your skin, this may cause stretch marks and it may also damage more easily
- skin wrinkling
- skin dryness
- the appearance of blood vessels under the surface of your skin
- changes to the colour of your skin
- increased body hair
- hair loss/lack of hair growth/damaged looking hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- application site irritation / pain
- redness
- rash or hives
- skin infection

In children also look out for the following symptoms:

- delayed weight gain
- slow growth

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- weakening of the bones through gradual loss of mineral (osteoporosis); additional tests may be needed after your medical examination to confirm if you have this condition

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly

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via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Betnovate

- Keep this medicine 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. Store in the original package. Protect from light. Protect from moisture.
- Keep the container tightly closed when not in use.
- Contents are flammable. Keep away from all sources of fire, flame and heat. Do not leave in direct sunlight.
- Do not throw away any 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 substance is betamethasone (as valerate). Each 10 ml contains 0.01 g of betamethasone(0.1 % w/w) as valerate.
- The other ingredients are: carbomer, isopropyl alcohol, sodium hydroxide and purified water.

What Betnovate looks like and contents of the pack

Betnovate is a colourless, hazy and slightly sticky solution. Within each carton is a specially designed 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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

GlaxoSmithKline (Ireland) Ltd, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer

Aspen, Bad Oldesloe GmbH, Industriestrasse 32 – 36, 23843 Bad Oldesloe, Germany.

This leaflet was last revised in April 2022.

Other sources of information

This package leaflet is available in formats that are suitable for the blind or partially sighted. Such formats are available on request.

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