Betacap™ Scalp Application

0.1% w/w cutaneous solution
betamethasone (as 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.

In this leaflet:
1. What Betacap Scalp Application is and what it is used for
2. What you need to know before you use Betacap Scalp Application
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1. WHAT BETACAP SCALP APPLICATION IS AND WHAT IT IS USED FOR

- Betacap Scalp Application is for use on the scalp to treat skin diseases including psoriasis (scaly, pink patches of thickened skin) and seborrhoeic dermatitis (scaly, itchy patches of skin).
- Betacap Scalp Application is suitable for use by **adults, the elderly and children over the age of one year.**
- The **active ingredient** in this product is betamethasone. This is one of a group of medicines called corticosteroids (which should not be confused with 'anabolic steroid' tablets or injections misused by some athletes).
- Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Betacap Scalp Application is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.
- Betamethasone is a strong and fast acting corticosteroid and is intended for use on the scalp which tends not to respond very well to weaker medicines of this type.
- Betamethasone works by reducing inflammation and calming down your immune system.
- The product also works as an antiseptic, and includes an emollient (moisturiser) to help make the scalp feel more comfortable.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BETACAP SCALP APPLICATION

Do not use Betacap Scalp Application:
- if you are **allergic (hypersensitive)** to betamethasone or any of the other ingredients of Betacap Scalp Application listed in Section 6;
- to treat any other skin problems, **especially skin infections**, as it may make them worse;
- to treat any scalp problem other than the one your doctor prescribed it for;
- on children **under one year** of age.

Warnings and precautions
Talk to your doctor or pharmacist before using Betacap Scalp Application.
- Tell your doctor if at any stage you think your scalp has become infected. Your doctor may advise you to stop using Betacap for a while and start using an alternative anti-microbial treatment instead.
- If you are treating **scalp psoriasis**, it is important that your doctor checks your progress regularly to avoid a possible complication that can occur (see Section 4).
- **Do not use this product excessively:**
  – avoid using this product continuously or frequently for long periods (weeks or months on end);

  – this is especially important for infants and young children, because long term use increases the chance of local and generalised side effects (see Section 4);
  – **for children** with scalp **seborrhoeic dermatitis**, treatment should normally be limited to no more than 7 days.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Take special care when using this product:
- Keep the product **away from your eyes and mouth**.
- Betacap is **highly flammable**. Do not use it near flames or ignition sources (e.g. burning cigarettes or anything else that might ignite it).
- If there is a worsening of your condition during use consult your prescriber - you may be experiencing an allergic reaction, have an infection or your condition may require a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using Betacap Scalp Application without consulting your prescriber unless your prescriber 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, please seek medical advice before restarting treatment.

Using other medicines
Betacap Scalp Application is not known to affect, or to be affected by, any other medicines.

Pregnancy and breast-feeding
It is unclear whether this product is safe for use during pregnancy and breast-feeding. Animal birth defects have occurred with similar medicines containing corticosteroids, so there may be a very small risk of these problems in humans. You should therefore not normally use this product if you are pregnant or breast-feeding unless your doctor has recommended you to do so.

Driving and using machinery
Using this product is not known to affect your ability to drive or use machinery.

3. HOW TO USE BETACAP SCALP APPLICATION

Use Betacap Scalp Application only on psoriasis and seborrhoeic dermatitis **affecting the scalp**.

Before using this bottle of Betacap Scalp Application for the first time, turn the bottle cap anti-clockwise to break the seal.

For adults and the elderly:
Repeat the following **twice a day**, morning and evening, until you notice an improvement in your scalp condition. On days when you shampoo your hair, apply Betacap Scalp Application **after drying** the hair:
- Carefully turn the bottle upside-down over your head, holding the nozzle against the part of the scalp to be treated.
- Gently squeeze the bottle until the affected area is coated with a thin layer of the preparation.
- Gently massage the application into the scalp to prevent it from running off.
- Allow the treated scalp to dry naturally. Do not use a hair drier.
- Your scalp will feel cool until the liquid has dried. The active ingredient is then left on your scalp.
- Always wash your hands after use.

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When you can see that your scalp condition is getting better, you can start to apply Betacap Scalp Application **less often**, only once a day or even less. The frequency of application should be reduced to the minimum necessary to keep your scalp condition under control.

For children (over one year old):

- Follow the same instructions as for adults (see above), but use the product **more sparingly**.
- Never apply more than is needed to cover the affected area.
- **Do not cover** the treated scalp with an airtight dressing.
- When treating seborrhoeic dermatitis in children, do not use the product for longer than 7 days.

If Betacap Scalp Application gets into the eyes it may cause damage. If it gets into the eyes, rinse immediately with plenty of water. If rinsing one eye, take care to avoid washing product into the other eye. If irritation persists tell your doctor or pharmacist.

Betacap Scalp Application is dangerous if swallowed. If someone swallows this product by mistake, take the following emergency action: if they are drowsy or unconscious, give nothing by mouth. If they are conscious, encourage them to drink 1 or 2 cups of milk or water (one cup in the case of a child), but do not carry on if they are vomiting. In all cases, take them to a doctor or hospital straight away. Take this leaflet and the container of Betacap Scalp Application with you.

If you apply too much Betacap Scalp Application, use a tissue to mop up any excess and stop it spreading onto uninvolved skin areas.

If you occasionally forget to use Betacap Scalp Application, do not worry, just carry on using it when you remember.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Betacap Scalp Application can cause side effects, although not everybody gets them. Betacap Scalp Application may cause the following side effects of unknown frequency (frequency cannot be estimated from the available data):

- Skin irritation may occur. If this happens stop using the product.
- Treating psoriasis with this type of product may cause the development of the pustular form of the disease (blisters filled with pus). This explains why careful supervision by your doctor is required if you are treating scalp psoriasis.
- Topical corticosteroids are usually well tolerated when used in the right amount and for the correct length of time. However, **prolonged, excessive use, particularly in children or on skin that is bandaged or wrapped up**, can cause local skin thinning (making the skin damage easily), and adrenal suppression (a type of hormone imbalance that causes generalised effects on the body). Stopping treatment normally corrects these side effects.
- Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after 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.
- Blurred vision.

If you are in any doubt about the treatment, or experience any of the above side effects or any other side effect not mentioned in this leaflet, **stop using** this product and tell your doctor or pharmacist.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE BETACAP SCALP APPLICATION

- Keep this medicine out of the sight and reach of children.
- Do not use Betacap Scalp Application after the expiry date shown on the bottle and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Always replace the cap tightly and return the bottle to the carton after use (to protect the contents from light).
- **Betacap Scalp Application is highly flammable**. Do not use it near flames or ignition sources.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Betacap Scalp Application contains:
The **active ingredient** is betamethasone (as betamethasone valerate) 0.1% w/w.
The **other ingredients** are macrogolglycerol cocoates, isopropyl alcohol, carbomer, sodium hydroxide and purified water.

What Betacap Scalp Application looks like and contents of the pack

- Betacap Scalp Application is a clear, colourless, slightly thickened liquid.
- The product is available in plastic bottles containing 100 ml, incorporating a specially designed nozzle applicator for convenient direct application to the scalp.

Marketing Authorisation holder:
Dermal Laboratories, Hitchin, Herts SG4 7QR.

Manufacturer:
Aeropak, Viking Road, Great Yarmouth, NR31 0NU, UK.

This Patient Information Leaflet was last revised in March 2024.

To listen to or request a copy of this leaflet in Braille, large print or audio, please call free of charge: 0800 198 5000 (UK only).
Please be ready to give the following information: Betacap, 00173/0149.
This is a service provided by the Royal National Institute of Blind People (RNIB).

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