

Package leaflet: Information for the user

Betamethasone + Salicylic Acid 0.05% w/w + 3% w/w ointment

betamethasone (as dipropionate 0.064%),
salicylic acid

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

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1. What this medicine is and what it is used for

This medicine contains two active ingredients, betamethasone dipropionate and salicylic acid. Betamethasone dipropionate is one of a group of medicines called topical corticosteroids. These medicines are put on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. 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. This medicine is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

Salicylic acid softens the top layer or scales on the surface of the skin, which are caused by your skin problem. This allows the betamethasone dipropionate to reach the diseased skin underneath to help heal it.

In adults and children, this medicine is used to treat skin conditions where the outer surface of the skin is covered by a layer of scales. Your ointment will remove the layer of scales and reduce the redness and itchiness caused by your skin problem.

2. What you need to know before you use this medicine

Do not use this medicine:

- if you have an allergy to betamethasone dipropionate, salicylic acid or any of the other ingredients of this medicine (listed in section 6).
- any other skin problem as it could make it worse especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, genital itching, nappy rash, cold sores, chickenpox or other skin conditions.

Warnings and precautions

If you have psoriasis, your doctor may want to review your treatment regularly. Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin.

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

This medicine should not be used under bandages or plasters.

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids use on the skin, especially in infants and children.

In adults, the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings 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 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 requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the ointment 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.

Children

If you use more than the correct amount of ointment and/or use it for longer than is recommended, it can affect your child's hormones. Rarely this may lead to:

- delayed growth and development
- puffiness or rounding of the face
- a build-up of pressure around the brain which can produce:
 - a bulging of the fontanelle (the soft spot in the top of the skull) in infants
 - a constant thumping headache
 - blurred vision or other visual disturbances

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 using this medicine.

3. How to take this medicine

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

Recommended dose

Usually for adults and children, a thin layer of ointment should be gently rubbed into the affected area of skin twice a day.

You should always follow these instructions when using this medicine:

- do not use the ointment on your face for more than 5 days
- do not use a large amount of ointment on large areas of the body for a long time (for example every day for many weeks or months)
- avoid getting the ointment in your eyes or inside your nose or mouth.

Use in children

Use as stated above. Do not use this ointment on any part of your child's body for more than 5 days. Do not put the ointment under your child's nappy, as this makes it easier for the active ingredients of the medicine to pass through the skin and possibly cause some unwanted effects.

If you take more of this medicine than you should

If you (or somebody else) accidentally swallow the ointment, it should not cause any problems. However, if you are worried, you should see your doctor. If you use the ointment more often than you should, or on large areas of your body, it can affect some of your hormones. In children this may affect their growth and development. It also may cause you to feel and/or be sick and to hear ringing in your ears. If you have not used the ointment as you were told to do and have used it too often and/or for a long time, you should tell your doctor or pharmacist.

If you forget to take this medicine

If you forget to use your ointment at the right time, use it as soon as you remember, then carry on as before.

If you stop using this medicine

If you have been using the ointment for a long time and your skin problem seems to have got better, you should not suddenly stop using the ointment. If you do, you may find that your skin becomes red and you may notice stinging or burning. To avoid this, you should speak to your doctor who will gradually reduce how often you need to use the ointment until you stop treatment altogether.

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.

Most people find that when the ointment is used correctly, it does not cause any problems. However, if you use the ointment more often than you should, it can cause the following:

- thinning of the skin, stinging, blistering, peeling, swelling, itching, burning, skin rash, dryness of the skin and you may notice red marks. This can happen more easily in infants and children.
- inflammation of the hair follicles, excessive hair growth, reduced skin pigmentation and allergic skin reactions.
- dermatitis (skin inflammation), a condition brought on by the skin reacting to an outside agent e.g. detergents, causing the skin to become red and itchy.
- blurred vision

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.

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. You can also report side effects directly via the Yellow Card Scheme (Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the 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 this medicine

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

After first opening this medicinal product can be used for 6 months if stored below 25°C.

Do not use this medicine after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

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

- The active substances are betamethasone dipropionate and salicylic acid. One gram of ointment contains 0.5mg of betamethasone (as betamethasone dipropionate 0.64mg) and 30mg of salicylic acid.
- The other ingredients are: paraffin, liquid; paraffin, white soft.

This medicine is a white, semi-transparent homogeneous ointment, packed in an aluminium tube with internal protective lacquer (epoxy phenolic lacquer) and protective membrane and a HDPE screw cap with piercing spike, in a carton box.

Pack size: 30g, 100g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last revised in March 2025.

PL56328/0005
UK/100040/IF2.1