

Alclometasone dipropionate 0.05% w/w Cream

The name of your medicine is alclometasone dipropionate 0.05% w/w cream which will be referred to as alclometasone throughout the rest of this leaflet.

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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2. What you need to know before you use alclometasone
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1. What alclometasone is and what it is used for

This medicine contains an active ingredient called alclometasone dipropionate which belongs to a group of medicines called topical corticosteroids. These medicines are used on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

In adults and children, this medicine is used to reduce redness and itchiness caused by certain skin problems (for example eczema and dermatitis):

- Eczema is a common skin disease, which causes the skin to become red and itchy.
- Dermatitis is a condition brought on by the skin reacting to outside agents e.g. detergents, causing the skin to become red and itchy.

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. Alclometasone dipropionate is classed as a **moderate** corticosteroid.

Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. What you need to know before you use alclometasone

Do not use this medicine:

- if you, or a child you are caring for, have ever had an allergic reaction to alclometasone or any of the other ingredients of this medicine (listed in section 6).
- for any other skin problems as it could make them worse, especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, cold sores, chickenpox, or skin infections (including bacterial, fungal and viral infections).
- in babies less than 4 weeks old with open wounds or large areas of broken or damaged skin (such as burns) without talking to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine:

- If you are pregnant, think you may be pregnant or if you are breast-feeding (see section Pregnancy, breast-feeding and fertility).
- If you use this medicine on large areas of the body for prolonged periods of time, especially when treating children, since it may increase the absorption of the product and the risk of toxicity.
- If you use this medicine on covered parts of the body. Do not use this product under occlusive dressing; the affected zone has to be in contact with the air and not covered by dressing, tight clothes or similar. In infants, a nappy can act as an occlusive dressing. You should wash your skin before changing the dressing.
- 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 cream 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.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this medicine burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

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.

This medicine contains propylene glycol

This medicine contains 250mg propylene glycol per gram of cream. Propylene glycol may cause skin irritation.

3. How to use alclometasone

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

For adults and children, apply a thin layer of this medicine to the affected area two or three times a day, unless otherwise instructed by your doctor. Ask your doctor about the duration of the treatment.

You must not use a large amount of this medicine in the same area for a long time (for example every day for many weeks and months).

Do not apply this medicine under dressings, such as a plaster or bandage, as this makes it easier for the active ingredient to pass through the skin and possibly cause some unwanted effects.

If the cream is for your child, do not use it under a nappy, as this makes it easier for the active ingredient to pass through the skin and possibly cause some unwanted effects.

Instructions for use:

1. Wash your hands
2. Apply a thin film of the cream and rub gently until it has all disappeared
3. Wash your hands, unless the cream is used to treat your hands.

If you use more of this medicine than you should

Tell your doctor if:

- you use this medicine more often than you should, or on large areas of your body as it can affect some of your hormones.
- you have not followed the dosage instructions or your doctors advice and have used this medicine too frequently or for a longer time than prescribed.
- you (or somebody else) accidentally swallows this medicine, however it should not produce any undesirable effects.

If you forget to use this medicine

If you forget to use your cream at the right time, use it as soon as you remember then carry on as before. Do not double the amount of cream used to make up for a forgotten dose.

4. Possible Side effects

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

Most people find that when the cream is used correctly, it does not cause any problems.

However, if you use more cream than you should, particularly on your face, it can cause:

- 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.
- This happens more easily in infants and children.
- 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 aclometasone

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 pack. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not throw away any medicines via wastewater. 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 this medicine contains

The active substance is aclometasone dipropionate 0.05% w/w.

The other ingredients are: propylene glycol, white soft paraffin, cetostearyl alcohol, glycetyl stearate PEG 100 stearate, polyoxyethylene (20) cetyl ether, sodium dihydrogen phosphate dihydrate, 4-chloro-M-cresol, phosphoric acid, purified water.

What this medicine looks like and contents of the pack

This medicine is a smooth, white to off white cream contained in a 50g aluminium tube with a screw cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Aspire Pharma Ltd.
Unit 4, Rotherbrook Court
Bedford Road
Petersfield
Hampshire
GU32 3QG
United Kingdom.

Manufacturer:

TIOFARMA B.V.
Benjamin Franklinstraat 5-10
3261 LW Oud-Beijerland
The Netherlands.

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