

Artwork Information

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PATIENT INFORMATION LEAFLET

Alphaderm® 1% & 10% w/w Cream

hydrocortisone and urea

Read all of this leaflet carefully before you start using this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

The information in this leaflet has been divided into the following sections:

1. What Alphaderm Cream is and what it is used for
2. Check before you use Alphaderm Cream
3. How to use Alphaderm Cream
4. Possible side effects
5. How to store Alphaderm Cream
6. Further information

1. What Alphaderm Cream is and what it is used for

Alphaderm Cream belongs to a group of medicines called topical corticosteroids. Corticosteroids (or steroids) are similar to natural substances the body produces. They can reduce inflammation, itching and thickening of the skin.

Alphaderm Cream contains a mild steroid called 'hydrocortisone'- this is often used to treat skin conditions such as eczema. The hydrocortisone fights the inflammation that causes redness, swelling and itchiness.

Alphaderm Cream also contains urea, the skin's natural moisturiser. This softens dry, scaly skin and helps the hydrocortisone to penetrate deeper into the skin and be more effective. The urea in Alphaderm Cream is mixed with white soft paraffin which forms a layer of oil on the surface of the skin. This oily layer helps prevent water from evaporating from the skin's surface which will reduce irritation, restore suppleness and improve the appearance of your skin.

2. Check before you use Alphaderm Cream

Do not use Alphaderm Cream:

- if you are allergic (hypersensitive) to hydrocortisone or urea or any of the ingredients of Alphaderm Cream (see Section 6 Further information)
- if you have acne, infected skin or red, inflamed skin on the face and mouth.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you use Alphaderm Cream.

Take special care with Alphaderm Cream

Before you use Alphaderm Cream tell your doctor:

- if you have moist or weeping skin
- if you have been using corticosteroids for a long period of time
- if you want to use Alphaderm Cream on your face or eyelids.

Do not use the cream under nappies or on the face or eyelids unless your doctor tells you to.

Special care is needed when using Alphaderm Cream on children, and it should not be used for longer than 7 days unless your doctor tells you to.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before you use Alphaderm Cream.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken/used any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

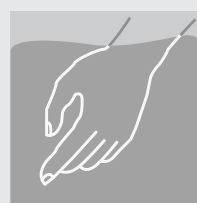
Ask your doctor or pharmacist for advice before taking any medicine.

There is not enough information to show that Alphaderm Cream can be used safely during pregnancy and breast-feeding. If you are pregnant or breast-feeding, only use Alphaderm Cream if advised by your doctor as there may be a very small risk to your baby.

3. How to use Alphaderm Cream

Always use Alphaderm Cream exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

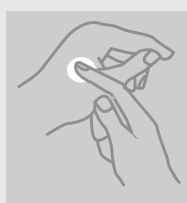
Using Alphaderm Cream is easy, just follow the instructions below:



wash the
affected
areas



rinse and
dry



then apply
a small
amount of
the cream
twice a day

Your doctor may tell you to cover this with a special 'occlusive' dressing, but this is not usually necessary.

The cream should not be used continuously for a long time. Talk to your doctor about this if you are not sure whether to continue using the cream.

What to do if you take more Alphaderm Cream than you should

Over-use of any steroid cream, especially for long periods, on large areas of skin, can result in the body absorbing too much steroid. This may occasionally lead to a thinning and weakening of the skin.

Over-use in children could result in a condition where the body produces less of its own natural steroids.

The cream is for external use only and should only be applied to the skin. If you accidentally swallow the cream this may make you feel sick; drink plenty of water or milk. You should tell your doctor at once or contact your nearest accident and emergency department. Show any left-over medicines or the empty container to the doctor.

If you forget to use Alphaderm Cream

If you forget to use the cream on any occasion, do not worry, just continue as normal.

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

Some do's and don'ts for Alphaderm Cream:

Do

use Alphaderm Cream as directed

Do

wash, rinse and dry affected area before applying Alphaderm Cream

Do

apply Alphaderm Cream twice daily - but sparingly each time

Don't

use Alphaderm Cream if you've had a past reaction to it or any of its ingredients

Don't

use Alphaderm Cream continuously for a long time

Don't

use Alphaderm Cream on acne, infected skin, moist or weeping skin, or on red inflamed skin on your face or mouth

4. Possible side effects

Do not worry. Like all medicines, Alphaderm Cream can cause side effects, although not everyone gets them.

Hydrocortisone creams like Alphaderm Cream sometimes cause the following side effects in some people:

- irritation of cracked or moist skin
- skin infections may spread or get worse
- red marks or lines may appear on the skin
- inflammation of the skin
- acne
- slight loss of pigment (colour) in the skin where the cream is used
- skin thinning may occur where the skin rubs together or in the nappy area of young children.

If you use Alphaderm Cream as your doctor tells you, it is unlikely to cause side effects.

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:

UK: The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

IE: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie, E-mail medsafety@hpra.ie.

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

5. How to store Alphaderm Cream

Keep out of the reach and sight of children.

Do not use Alphaderm Cream after the expiry date which is stated on the carton and on the base of the tube. The expiry date refers to the last day of that month.

Do not store Alphaderm Cream above 25°C.

Do not use Alphaderm Cream if you notice a change in the colour or feel of the cream.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What is in Alphaderm Cream?

The active ingredients in this medicine are hydrocortisone 1% w/w and urea 10% w/w contained in white soft paraffin.

The other ingredients are isopropyl myristate, maize starch, glyceryl tribehenate, palmitic acid, sorbitan laurate and polyoxyethylene fatty glyceride.

What Alphaderm Cream looks like and contents of the pack

Alphaderm Cream is a white cream.

Alphaderm Cream comes in aluminium tubes of 30g (grams) and 100g.

Marketing Authorisation Holder and Manufacturer

The marketing authorisation holder is: Alliance Pharmaceuticals Ltd, Avonbridge House, Chippenham, Wiltshire, SN15 2BB, UK.

Alphaderm Cream is manufactured by: Laboratoires Chemineau, 93 Route de Monnaie, BP 16, 37210, Vouvray, France.

The information in this leaflet applies only to Alphaderm Cream. If you have any questions or you are not sure about anything, ask your doctor or a pharmacist.

This leaflet was last approved: 1st February 2015

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