



## Modrasone<sup>®</sup> Cream

Alclometasone Dipropionate

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### PACKAGE LEAFLET: INFORMATION FOR THE USER



**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

1. What Modrasone Cream is and what it is used for
2. What you need to know before you use Modrasone Cream
3. How to use Modrasone Cream
4. Possible side effects
5. How to store Modrasone Cream
6. Contents of the pack and other information

#### 1. What Modrasone Cream is and what it is used for

Modrasone Cream 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, Modrasone Cream 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.

#### 2. What you need to know before you use Modrasone Cream

##### Do not use Modrasone Cream:

- if you, or a child you are caring for, have ever had an allergic reaction to Modrasone Cream 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).

##### 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.

##### Modrasone Cream contains propylene glycol

This may cause skin irritation.

#### 3. How to use Modrasone Cream

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

**The usual dose for children and adults, a thin layer of Modrasone Cream gently massaged into the affected area two or three times a day.**

- Gently massage the cream until it disappears.
- Your doctor may tell you to use Modrasone Cream in a different way. If so, follow your doctor's instructions carefully.
- 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.
- You must not use a large amount of Modrasone Cream in the same area for a long time (for example every day for many weeks and months).
- Do not put Modrasone Cream under dressing, 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 you use more Modrasone Cream than you should

Tell your doctor if:

- you use the cream 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 doctor's advice and have used the cream too frequently or for a longer time than prescribed.
- you (or somebody else) accidentally swallows the cream, however it should not produce any undesirable effects.

##### If you forget to use Modrasone Cream

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 outside agent e.g. detergents, causing the skin to become red and itchy.

This happens more easily in infants and children.

##### 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 at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

#### 5. How to store Modrasone Cream

- Keep this medicine out of the sight and reach of children.
- The cream should not be stored above 25°C.
- 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 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 Modrasone Cream contains

The active substance is alclometasone dipropionate 0.05% w/w. The other ingredients are: Propylene glycol Ph.Eur; White Soft Paraffin BP; Cetostearyl Alcohol BP; Glyceryl Stearate PEG 100 stearate; Polyoxyethylene (20) Cetyl Ether; Sodium Dihydrogen Phosphate Dihydrate Ph.Eur; 4-Chloro-M-Cresol BP; Phosphoric Acid Ph.Eur; Purified Water Ph.Eur.

##### What Modrasone Cream looks like and contents of the pack

Modrasone Cream is a smooth, white to off white cream. It is available in tubes containing 50 g.

##### Marketing Authorisation Holder and Manufacturer

The holder of the Marketing Authorisation is:

Merck Sharp & Dohme Limited,  
Hertford Road, Hoddesdon,  
Hertfordshire, EN11 9BU, UK.

The manufacturer is:

Schering-Plough Labo NV,  
Heist-op-den-Berg, Belgium.

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