

Modrasone®
Cream 0.05% w/w

Alclometasone Dipropionate

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

In this leaflet:

1. What Modrasone Cream is and what it is used for
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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 including eczema.

Eczema is a common skin disease, which causes the skin to become red and itchy.

2 BEFORE YOU USE MODRASONE CREAM

Do not use Modrasone Cream

- if you, or the child you are caring for, have ever had an allergic reaction to Modrasone Cream or any of its active or inactive ingredients.
- 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.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant or breast-feeding, before you start using Modrasone Cream.

Important information about some of the ingredients of Modrasone Cream

Modrasone Cream contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and propylene glycol which may cause skin irritation. Modrasone Cream also contains chlorocresol which may cause allergic reactions.

3 HOW TO USE MODRASONE CREAM

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

- Usually, for adults and children, a thin layer of Modrasone Cream should be 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 or months).
- Do not put Modrasone Cream under a 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

If you (or somebody else) accidentally swallow the cream, it should not produce any undesirable effects. However, if you are worried, you should speak to your doctor.

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 doctors advice and have used the cream too frequently or for a longer time than prescribed.

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

Most people find that when the cream is used correctly, it does not cause any problems. However, if you use the cream more often than you should, particularly on your face, it can cause thinning of the skin and red marks.

This happens more easily in infants and children.

If you are worried, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5 HOW TO STORE MODRASONE CREAM

Keep out of the reach and sight of children.

Do not use Modrasone Cream after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

Modrasone Cream should not be stored above 25°C.

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 FURTHER INFORMATION

What Modrasone Cream contains

The active substance is alclometasone dipropionate 0.05% w/w. The other ingredients are: propylene glycol; white soft paraffin; cetostearyl alcohol; glyceryl stearate PEG 100 stearate; macrogol cetostearyl ether; sodium dihydrogen phosphate dihydrate; chlorocresol; phosphoric acid; purified water.

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 Ireland (Human Health) Limited,
Red Oak North, South County Business Park, Leopardstown, Dublin 18, Ireland.

The manufacturer is:

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

Modrasone Cream is distributed on behalf of

Teva Pharmaceuticals Ireland by:

United Drug Distributors, Magna Drive,
Magna Business Park, City West Road,
Dublin 24, Ireland.

This leaflet was last approved in April 2014.