

Package leaflet: Information for the user

Modrasone® Ointment 0.05% w/w Alclometasone Dipropionate

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

1. What Modrasone Ointment is and what it is used for

Modrasone Ointment 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 Ointment 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 Ointment

Do not use Modrasone Ointment

- if you are allergic to alclometasone dipropionate 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 around the mouth, cold sores, chickenpox, or skin infections (including bacterial, fungal and viral infections).

Warnings and precautions

Talk to your doctor or pharmacist before using Modrasone Ointment if you are concerned about any of the following:

- This medicine should not be used under nappies, bandages or plasters.
- Do not apply to the area around the eye as this may cause glaucoma.

- Use of topical corticosteroids in children and adults can cause Cushing's syndrome (fatigue, muscle weakness, weight gain, high blood pressure, rounded face with a reddish complexion).
- HPA axis suppression in children and adults (fatigue, depression, anxiety, and suppressed immune system) can occur with large doses of corticosteroids, recovery is usually prompt on stopping treatment.
- If irritation develops, stop treatment.
- Antifungal or antibacterial medicines should be used if a skin infection is present.
- Corticosteroids may cause cataract development.
- Modrasone ointment is not for use in the eye.

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.

Children

If the ointment is used more often than it should, or more than prescribed, it can affect some of your child's hormones. This may affect their growth and development.

- Do not use on children for longer than 2 weeks.
- High pressure in the skull (bulging fontanelle, headaches, swelling of the eyes) has been reported in children using corticosteroids.
- Children may be more likely to develop side effects.

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 Ointment contains propylene glycol

This medicine contains 20 mg propylene glycol in each gram of ointment. Propylene glycol may cause skin irritation.

Do not use this medicine 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

3. How to use Modrasone Ointment

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

- For adults and children, a thin layer of Modrasone Ointment gently massaged into 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 Modrasone Ointment in the same area for a long time (for example every day for many weeks or months).
- Do not apply Modrasone Ointment 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 the ointment 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 before applying the ointment
2. Apply a thin film of the ointment and rub gently until it has all disappeared

3. Wash your hands after applying the ointment to the affected area, unless the ointment is used to treat your hands.

If you use more Modrasone Ointment than you should

Tell your doctor if;

- you use the ointment 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 ointment too frequently or for a longer time than prescribed.
- you (or somebody else) accidentally swallows the ointment, it should not produce any undesirable effects. However, if you are worried, you should speak to your doctor.

If you forget to use Modrasone Ointment

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

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 more ointment 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.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Modrasone Ointment

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

Do not use Modrasone Ointment 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.

Do not be store above 25°C.

Do not throw away any medicines 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. Contents of the pack and other information

What Modrasone Ointment contains

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

The other ingredients are hexylene glycol, propylene glycol monostearate, white beeswax and white soft paraffin.

What Modrasone Ointment looks like and contents of the pack

Modrasone Ointment is a colourless to light yellow ointment contained in a 50g aluminium tube with a screw cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

European Regulatory Affairs t/a Ivowen
3 Anglesea St.
Clonmel
Co. Tipperary
E91 D6C5
Ireland

Manufacturer

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

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