

Package leaflet: Information for the patient

Dermasone Cream

Clobetasol Propionate

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

1. What Dermasone is and what it is used for

Dermasone contains a medicine called Clobetasol. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

Dermasone is used to help reduce the redness and itchiness of certain skin problems. These skin problems include frequently relapsing eczema, psoriasis, excluding widespread plaque psoriasis, lichen planus, discoid lupus erythematosus, dermatitis.

2. What you need to know before you use Dermasone

Do not use Dermasone:

- if you are allergic (hypersensitive) to Clobetasol or any of the other ingredients of this medicine (listed in Section 6)
- on a child under 1 year of age
- to treat any of the following skin problems, it could make them worse:
 - Acne

- severe flushing of skin on and around your nose (rosacea)
- spotty red rash around your mouth (perioral dermatitis)
- itching around your anus or genitals (penis or vagina)
- infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
- itchy skin which is not inflamed
- widespread plaque psoriasis, except single lesions.

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using Dermasone.

Warnings and precautions

Talk to your doctor or pharmacist before using Dermasone if:

- you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with Dermasone especially if you have been using Dermasone for a prolonged time or repeatedly.
- you use other oral/topical medication containing corticosteroids or medication intended to control your immune system (e.g. for autoimmune disease or after a transplantation). Combining Dermasone with these medicines may result in serious infections.

- you have previously had an allergic reaction with another steroid.
- you are applying the cream under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much cream.

- make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.
- you are applying the cream on broken or damaged skin or within skin folds.
- you are applying to a large surface area.
- you have psoriasis, your doctor will want to see you more often.

- you are using around a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the cream repeatedly enters the eye.

- you are applying to thin skin such as the face, as Dermasone may cause skin thinning. Use on the face should be limited to 5 days. Dressings or bandages should not be used on the face where the cream is applied.

Contact your doctor if you experience blurred vision or other visual disturbances.

If an infection develops during the use of this medicine, talk to your doctor or pharmacist.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Children

- Do not use this medicine in children under 1 year of age.
- Avoid continuous treatment for a long period of time in infants and children over 1 year of age, as their skin is thinner than adults and as a result may absorb larger amounts.
- Use on children should be limited to 5 days and reviewed weekly.
- Dressings or bandages should not be used on children where the cream is applied.

Other medicines and Dermasone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicine, especially if you are taking ritonavir and itraconazole medications.

Pregnancy, breast-feeding and fertility

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.

If you do use Dermasone when breast-feeding, do not use it on your breast area to ensure that the baby does not accidentally get Dermasone in their mouth.

Driving and using machines

Dermasone cream is a medicinal product for topical application. Does not affect the ability to drive and use machines.

Dermasone contains Propylene glycol.

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.

Dermasone contains Methyl paraben and Propyl paraben.

Methyl paraben and Propyl paraben may cause allergic reactions (possibly delayed).

3. How to use Dermasone

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

Using this medicine

- You usually apply a thin layer of Dermasone once or twice a day. This may be reduced as your skin begins to get better, or stopped when better. Your doctor may prescribe a weaker steroid for you to use instead.
- If you are also using an emollient (moisturizer), allow time for Dermasone to be absorbed into your skin before applying the emollient.
- This cream is for use on your skin only.
- Do not use for more than 4 weeks without talking to your doctor. If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment.
- If your skin problem worsens or does not improve within 2 to 4 weeks, talk to your doctor.
- The germs that cause infections like the warm and moist conditions under dressings. If directed to cover the treated area with a dressing, always clean the skin before a fresh dressing is put on to help prevent infection of the skin beneath the dressing.
- If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.

Guidance on how to apply the cream

Age	Number of fingertip units needed						
	Face and neck	Arm	Hand	Leg	Foot	Front	Back including buttocks
1-2 years	1 ½	1 ½	1 ½	2	2	2	3
3-5 years	1 ½	2	2	3	3	3	3 ½
6-10 years	2	2 ½	2 ½	4 ½	4 ½	3 ½	5
For adolescents (≥12 years old) and adults	2 ½	3	1	6	2	7	7

Do not worry if you find you need a little more or less than this. It is only a rough guide.

Use in children

- Do not use this medicine on children under 1 year of age.
- It is especially important in children not to exceed the prescribed amount.
- A course of treatment for a child over the age of 1 year should not normally last more than 5 days unless your doctor has told you to use it for longer. Your doctor may want to see the child every week, whilst using the cream.
- Dressings or bandages should not be used on children where the cream is applied.

If you have psoriasis

If you have thick patches of psoriasis on your elbows or knees, your doctor may suggest applying the cream under an airtight dressing. It will only be at night to help the cream to start working. After a short period of time you will then apply the cream as normal.

If you apply Dermasone to your face

You should only apply the cream to your face if your doctor tells you to. It should be limited to only 5 days as the skin on your face thins easily. Dressings or bandages should not be used on the face where the cream is applied. **Do not let the cream get into your eyes.** If it does, wash it out with plenty of water.

If you use more Dermasone than you should

If you apply too much or if accidentally swallowed, it could make you ill. Talk to your doctor or go to hospital as soon as possible.

If you forget to use Dermasone

If you forget to apply your cream, apply it as soon as you remember. If it is close to the time you are next meant to apply it, wait until this time. Do not apply extra Dermasone to make up for a missed dose.

If you stop using Dermasone

If you use Dermasone regularly make sure you talk to your doctor before you stop using it as your condition may get worse if stopped suddenly.

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.

Stop using Dermasone and tell your doctor immediately if:

- you find that your skin problem gets worse, you develop a generalized rash or your skin becomes swollen during treatment. You may be allergic to the cream, have an infection or need other treatment.
- you have psoriasis and get raised bumps with pus under the skin. This can happen during or after the treatment and is known as pustular psoriasis.

Other side effects you may notice when using Dermasone include:

Common (may affect up to 1 in 10 people)

- a feeling of burning, pain, irritation or itching where the cream is applied.

Uncommon (may affect up to 1 in 100 people)

- skin thinning, this may cause stretch marks
- blood vessels under the surface of your skin may become more noticeable.

Very Rare (may affect up to 1 in 10,000 people)

Use of Dermasone for a long period of time, or use under an airtight dressing, may cause the following symptoms:

- increased weight
- moon face, rounding of the face
- obesity
- skin thinning
- skin wrinkling
- skin dryness
- changes to the color of your skin
- increased body hair
- hair loss/lack of hair growth/damaged looking hair

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- application site irritation/pain
- redness
- rash or hives
- if you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis
- skin infection
- acne

In children, also look out for the following symptoms:

- delayed weight gain
- slow growth

Very rare side effects that may show up in blood tests or when your doctor gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (cataract)
- increased pressure in the eye (glaucoma)
- vision problems caused by detachment of the retina in the eye (central serous chorioretinopathy)
- weakening of the bones through gradual loss of mineral (osteoporosis); additional tests may be needed after your medical examination to confirm if you have this condition

Not Known (frequency cannot be estimated from the available data)

- blurred vision

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

5. How to store Dermasone

- 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 tube and the outer box. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from humidity.
- Do not use this medicine if you notice visible signs of deterioration.
- 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 Dermasone contains

The active ingredient is Clobetasol propionate. Each 1 g contains 0.5 mg of clobetasol propionate (0.05% w/w).

The other ingredients are emulsifying wax, paraffin, propylene glycol, methyl paraben, propyl paraben, imidazolidinyl urea, water.

What Dermasone looks like and contents of the pack

Dermasone comes in a tube containing 15 g of white cream, packed in a carton.

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Lebanon

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Contact us: pharmaline@maliagroup.com

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Dermasone Reg. N° Lebanon 26693/89

<p>This is a medicament:</p> <ul style="list-style-type: none">- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.- The doctor and the pharmacist are experts in medicine, its benefits and risks.- Do not by yourself interrupt the period of treatment prescribed for you.- Do not repeat the same prescription without consulting your doctor.- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers
Union of Arab Pharmacists**

The leaflet was last revised in March 2022