

CLODERM® Cream

Clobetasol Propionate 0.05% (w/w)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider 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, health care provider or pharmacist.

In this leaflet:

1. What **CLODERM®** is and what it is used for
2. Before you take **CLODERM®**
3. How to take **CLODERM®**
4. Possible side effects
5. How to store **CLODERM®**
6. Further information

1. What **CLODERM®** is and what it is used for

- **Pharmaco-therapeutic group:**

CLODERM® contains a medicine called clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

- **Therapeutic indications:**

CLODERM® is used to help reduce the redness and itchiness of certain skin problems. These skin problems include eczema, psoriasis, lichen planus, discoid lupus, dermatitis and other skin conditions that have not responded to milder steroid creams or ointments.

2. Before you take **CLODERM®**

a. Do not take **CLODERM®**

Do not take this medicine and tell your doctor if:

- if you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of this medicine
- on a child under 1 year old
- 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 back passage or private parts
 - infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
 - itchy skin which is not inflamed

Do not use if any of the above apply to you? If you are not sure, talk to your doctor or pharmacist before using **CLODERM®**. If you are not sure, talk to your doctor or pharmacist before taking **CLODERM®**.

b. Take special care with **CLODERM®**

Check with your doctor or pharmacist before taking your medicine if:

- 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.
- You have psoriasis; your doctor will want to see you more often.
- You are applying the cream on broken skin or within skin folds.
- Using for a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- You are applying to a large surface area or within the skin folds.
- 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 or on children 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. Use on the face should be limited to 5 days.
- Dressing or bandages should not be used on children or on the face where the cream is applied.

c. Taking other medicines, herbal or dietary supplements

Tell your doctor or pharmacist if you are taking, have recently taken

or might take any other medicine, including herbal medicines, especially if you are taking rifamavir and itraconazole medications. Also medicines you can buy without prescription.

d. 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.

e. Driving and using machines

You may feel drowsy or sleepy while taking this medicine or in the morning after taking this medicine. If this happens, do not drive or use any tools or machines.

f. Important information about some of the ingredients of **CLODERM®**

CLODERM® Cream contains propylene glycol, cetyl alcohol and chlorocresol. Propylene glycol may cause skin irritation. Cetyl alcohol may cause local skin reactions (e.g. contact dermatitis). Chlorocresol may cause allergic reactions.

3. How to take **CLODERM®**

Always take **CLODERM®** exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

• Using this medicine

• You usually apply a thin layer of **CLODERM®** 1 or 2 times a day. This may be reduced as your skin begins to get better, or stopped when better.

• This cream is for use on your skin only.

• Do not use on large areas of the body for a long time (such as every day for many weeks or months). If you need treatment for a long time, your doctor may decide you need to use a milder cream or ointment

- The germs that cause infections like warm and moist conditions under dressings so always clean the skin before a fresh dressing is put on.

• If you are applying the cream on someone else make sure you wash your hands after use or wear disposable plastic gloves.

• If your skin problem does not improve in 2 to 4 weeks, talk to your doctor.

• Guidance on how to apply the cream

1- Wash your hands.

2- Apply a thin layer to the affected area(s) and gently rub into the skin until it has all disappeared. You can measure how much **CLODERM®** to use with your fingertip. For children you will need to use less cream but still use an adult finger to measure out the fingertip unit.

3- Unless you are meant to apply the cream to your hands as a part of the treatment, wash them again after using the cream.

• For an adult

Face and neck: 2 ½ fingertip units.

Back: 7 fingertip units.

Front: 7 fingertip units.

One arm (not including the hand): 3 fingertip units.

Both sides of one hand: 1 fingertip unit.

One leg (not including the foot): 6 fingertip units

One foot: 2 fingertip units.

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

• For a child aged 1 – 10

Number of fingertip units needed					
Child's age	Face and neck	Arm and hand	Leg and foot	Front	Back including buttocks
1-2 years	1 ½	1 ½	2	2	3
3-5 years	1 ½	2	3	3	3 ½

6-10 years	2	2 ½	4 ½	3 ½	5
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• Do not use it 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 should not normally last more than 5 days - unless your doctor has told you to use it for longer. The doctor may want to see the child every week, whilst using the cream.

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 **CLODERM® 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. Do not let the cream get into your eyes. If it does, wash it out with plenty of water.

a. If you take more **CLODERM® than you should**

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

b. If you forget to take **CLODERM®**

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.

• If you stop taking **CLODERM®**

If you use **CLODERM®** 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 product, ask your doctor, health care provider or pharmacist.

4. Possible side effects

Like all medicines, **CLODERM®** can cause side effects, although not everybody gets them.

Stop using **CLODERM® and tell your doctor immediately if:**

- You find that your skin problem gets worse, you develop a generalised 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 **CLODERM® 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)

- Stretch marks may develop.

Veins under the surface of your skin may become more noticeable.

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

- An increased risk of infection
- An allergic skin reaction where the cream is applied
- Rash, itchy bumps or redness of the skin
- Thinning and dryness of your skin and it may also damage or wrinkle more easily
- An increase or reduction in hair growth or hair loss and changes in skin colour.
- Weight gain, rounding of the face
- Delayed weight gain or slowing of growth in children
- Bones can become thin, weak and break easily
- Cloudy lens in the eye (cataract) or increased pressure in the eye (glaucoma)
- Increased blood sugar levels or sugar in the urine
- High blood pressure

5. How to store **CLODERM®**

- Keep out of the reach and sight of children.

- Store below 30°C.

- Discard the content after one month from first opening.

- Do not use **CLODERM®** after the expiry date (Exp. Date) which is stated on the outer pack. The expiry date refers to the last day of that month.

- 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

a. What **CLODERM® contains**

• The active substance: Clobetasol propionate.

Clobetasol Propionate (0.05% w/w).

• The other ingredients are: Emulsifying Wax, Liquid Paraffin, White Bees Wax, Cetyl Alcohol, Propylene Glycol, Cetomacrogol 1000, Glycerol Monostearate, Citric Acid, Trisodium Citrate, Chlorocresol, Purified water.

b. What **CLODERM® looks like and contents of the pack**

- Dosage form: Cream.

- Physical Description: White homogenous cream with phenolic odor.

- Pack sizes: **CLODERM® Cream** is available in 15 & 25g tubes.

- **CLODERM® Cream** is packed in Lacquered Aluminum Tubes packed in a carton outer pack box with a multi folded leaflet.

c. Marketing Authorization Holder and Manufacturer

The United Pharmaceutical Mfg. Co. Ltd.

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e. To report any side effect(s):

• Saudi Arabia:

- National Pharmacovigilance & Drug Safety Centre (NPC):

• Fax: +966-11-205-7662

• Call NPC at +966-11-2038222, Ext.: 2317-2356-2353-2354-2334-2340.

• Toll free phone : 8002490000

• E-mail: npc.drug@sfdg.gov.sa

• Website: www.sfdg.gov.sa/npc

• Other GCC States:

- Please contact the relevant competent authority.

f. Council of Arab Health Ministers

This is a medication

• 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 medication.

• 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 medication out of the reach of children.

COUNCIL OF ARAB HEALTH MINISTERS

UNION OF ARAB PHARMACISTS

g. This patient information leaflet is approved by the Saudi Food and Drug Authority.

- Keep out of the reach and sight of children.

