

## PATIENT INFORMATION LEAFLET (PIL)

### PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

# CLOBETASOL 0.05%w/w CREAM

## Clobetasol propionate

**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 health care provider.
- \* 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

### **In this leaflet:**

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## **1. WHAT CLOBETASOL CREAM IS AND WHAT IT IS USED FOR**

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

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

## **2. BEFORE YOU USE CLOBETASOL CREAM**

Do not use this product:

- If you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of this medicine.
- 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 healthcare provider before using Clobetasol.

### **Warning and precautions**

Talk to your doctor or pharmacist before using Clobetasol if:

- You have previously had an allergic reaction with another steroid.
- You are applying the cream under an airtight dressing.  
(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 for 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 Clobetasol 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 health care provider before using this medicine.

### **Children**

Do not use this medicine in children below 12 years of age.

### **Other medicines and Clobetasol**

Tell your health care provider 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 health care provider for advice before taking this medicine.

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

## **3. HOW TO USE CLOBETASOL CREAM**

Always use this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

### **Using this medicine**

- Apply a thin layer of Clobetasol once or twice a day. This may be reduced as your skin begins to get better or stopped when better.
- If you are also using an emollient (moisturiser), allow time for Clobetasol 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 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.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Clobetasol cream can cause side effects, although not everybody gets them.

### **Stop using Clobetasol 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 that you may notice when using Clobetasol include:**

**Common (Affecting up to 1 in 10 people)**

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

**Uncommon (Affecting up to 1 in 100 people)**

- skin thinning, this may cause stretch marks

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- blood vessels under the surface of your skin may become more noticeable.

**Very Rare (Affecting up to 1 in 10,000 people)**

Use of Clobetasol 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 colour 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; skin infection; acne.

Very rare side effects that may show up in blood tests or when your health care provider 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)
- weakening of the bones through gradual loss of mineral (osteoporosis)

**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 healthcare provider. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

**5. HOW TO STORE CLOBETASOL CREAM**

Keep all medicines out of the reach of children.

Do not use this medicine after the expiry date which is stated on the carton after 'Exp. Date' used for expiry date. The expiry date refers to the last day of that month.

Store below 30°C, in a dry place.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. FURTHER INFORMATION**

**What Clobetasol cream contains:**

The active ingredient is clobetasol propionate.

**What Clobetasol cream looks like and contents of the pack:**

25g cream in a tube, placed in a carton with insert.

**Supplier and Manufacturer**

Fidson Healthcare Plc,  
Km. 38, Lagos-Abeokuta Expressway,  
Sango Ota, Ogun State  
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