

## **Patient Information**

### **Clobetasol Propionate Spray, 0.05%**

**(kloe-BEE-tah-sahl PRO-pee-oh-nate)**

**Important: For use on skin only. Do not get clobetasol propionate spray near or in your eyes, mouth, or vagina.**

Read the Patient Information that comes with clobetasol propionate spray before you start using it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

#### **What is Clobetasol Propionate Spray?**

Clobetasol propionate spray is a prescription corticosteroid medicine used to treat adults with moderate to severe plaque psoriasis that affects up to 20% of the body's skin surface. Clobetasol propionate spray is for use on the skin only (topical).

- Clobetasol propionate spray should only be used for the shortest amount of time needed to treat your plaque psoriasis.
- Do not use more than 26 sprays for each application or more than 52 sprays in 1 day.
- You should not apply more than 59 mL (2 fluid ounces) of clobetasol propionate spray to your skin in 1 week.

#### **You should not use Clobetasol Propionate Spray:**

- on your face, underarms (armpits), or groin areas
- if you have thinning of the skin (atrophy) at the treatment site
- to treat rosacea or a rash around the mouth (perioral dermatitis)

It is not known if clobetasol propionate spray is safe and effective in children under 18 years of age. Clobetasol propionate spray should not be used in children under 18 years of age.

#### **What should I tell my doctor before using Clobetasol Propionate Spray?**

##### **Before you use Clobetasol Propionate Spray, tell your doctor if you:**

- have a skin infection. You may need medicine to treat the skin infection before you use clobetasol propionate spray.
- plan to have surgery
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if clobetasol propionate spray will harm your unborn baby.
- are breast-feeding or plan to breast-feed. It is not known if clobetasol propionate spray passes into your breast milk. Talk to your doctor about the best way to feed your baby if you use clobetasol propionate spray.

**Tell your doctor about all the medicines you take**, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take other corticosteroid medicines by mouth or use other products on your skin that contain corticosteroids. Ask your doctor or pharmacist if you are not sure.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

### **How should I use Clobetasol Propionate Spray?**

- Use clobetasol propionate spray exactly as your doctor tells you to use it.
- Your doctor should tell you how much clobetasol propionate spray to use and where to apply it.
- Clobetasol propionate spray is for use on skin only. Do not get clobetasol propionate spray near or in your eyes, mouth, or vagina.
- You should not use clobetasol propionate spray on your face, underarms (armpits), or groin areas.
- Apply clobetasol propionate spray 2 times each day.
- Apply only enough clobetasol propionate spray to cover the affected skin areas. Rub in gently and completely.
- Wash your hands after using clobetasol propionate spray.
- Throw away any unused clobetasol propionate spray.
- Do not bandage or cover your treated areas unless your doctor tells you to.
- Tell your doctor if your skin condition is not getting better after 2 weeks of using clobetasol propionate spray. Your doctor may tell you to apply clobetasol propionate spray to certain areas of your skin for up to 2 more weeks if needed. You should not use clobetasol propionate spray for more than 4 weeks unless your doctor tells you to. This can increase your risk of serious side effects.

See the “Instructions for Use” at the end of the Patient Information for detailed information about the right way to apply clobetasol propionate spray.

### **What should I avoid while using Clobetasol Propionate Spray?**

- **Clobetasol propionate spray is flammable.** Avoid heat, flames or smoking while applying clobetasol propionate spray to your skin.

### **What are the possible side effects of Clobetasol Propionate Spray?**

- **Clobetasol propionate spray can pass through your skin.** Too much clobetasol propionate spray passing through your skin can cause your adrenal glands to stop working. Your doctor may do blood tests to check how well your adrenal glands are working.

### **The most common side effects with Clobetasol Propionate Spray include:**

- burning at treated site

- upper respiratory tract infection
- runny nose
- sore throat
- dry, itchy, and reddened skin

If you go to another doctor for illness, injury or surgery, tell that doctor you are using clobetasol propionate spray.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of clobetasol propionate spray. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or visit our website at [www.lupinpharmaceuticals.com](http://www.lupinpharmaceuticals.com).**

#### **How should I store Clobetasol Propionate Spray?**

- Store clobetasol propionate spray at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not store clobetasol propionate spray above 86°F (30°C).
- Do not freeze or refrigerate clobetasol propionate spray.
- Keep the bottle of clobetasol propionate spray tightly closed.
- Keep away from heat or flame

**Keep Clobetasol Propionate Spray and all medicines out of the reach of children.**

#### **General information about Clobetasol Propionate Spray.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use clobetasol propionate spray for a condition for which it was not prescribed. Do not give clobetasol propionate spray to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about clobetasol propionate spray. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about clobetasol propionate spray that is written for health professionals.

#### **What are the ingredients in Clobetasol Propionate Spray?**

**Active ingredient:** clobetasol propionate

**Inactive** ingredients: alcohol, isopropyl myristate, sodium lauryl sulfate, and undecylenic acid

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**Parts of Clobetasol Propionate Spray (See Figure A)**



**Figure A**

When you receive clobetasol propionate spray the Directional Spray Nozzle is in the “locked” position with the nozzle pointing downwards. (See **Figure B**)



Front View



**Figure B**

Side View

**How to apply Clobetasol Propionate Spray:**

**Step 1:** To unlock the Directional Spray Nozzle, hold the clobetasol propionate spray bottle and sides of the Pump Top with one hand. Use your other hand to turn the Directional Spray Nozzle to either the right or the left (**See Figure C**). The spray will come out through the opening at the end of the Directional Spray Nozzle.



**Figure C**

**Step 2:** To apply clobetasol propionate spray, point the Directional Spray Nozzle to the affected area. To spray, push down on the Pump Top. Apply clobetasol propionate spray to the affected area as instructed by your doctor. (See **Figure D**)



**Figure D**

**Step 3:** Spray only enough clobetasol propionate spray to cover the affected area, for example, the elbow (See **Figure E**). Rub in clobetasol propionate spray gently and completely.



**Figure E**

- You should not apply clobetasol propionate spray to your face, underarms or groin. Avoid contact with your eyes and lips.
- To apply to your scalp, part your hair at the area where clobetasol propionate spray is to be applied. Spray directly on the affected area, and then rub in gently and completely (See **Figure F**)



**Figure F**

- Repeat Steps 2 and 3 to apply clobetasol propionate spray to other affected areas as instructed by your doctor.

**Step 4:** After applying clobetasol propionate spray, return the Directional Spray Nozzle to the “locked” position. (See **Figure G**)



**Figure G**

**Step 5:** Wash your hands after applying clobetasol propionate spray.

This Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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