PATIENT INFORMATION Desoximetasone Topical Spray, 0.25% (des-OX-i-MET-a-sone)

Important information: Desoximetasone topical spray, 0.25% is for use on skin only. Do not get desoximetasone topical spray, 0.25% near or in your eyes, mouth or vagina.

What is Desoximetasone Topical Spray, 0.25%?

- Desoximetasone topical spray, 0.25% is a prescription corticosteroid medicine used to treat plaque psoriasis of the body in people 18 years of age and older.
- You should not use desoximetasone topical spray, 0.25% on your face, underarms (armpits), or groin areas.
- It is not known if desoximetasone topical spray, 0.25% is safe and effective in children under 18 years of age. Desoximetasone topical spray, 0.25% should not be used in children under 18 years of age.

Before you use Desoximetasone Topical Spray, 0.25%, tell your doctor if you:

- are allergic to any of the ingredients in desoximetasone topical spray, 0.25%. See the end of this leaflet for a list of the ingredients in desoximetasone topical spray, 0.25%.
- have a skin infection. You may need medicine to treat the skin infection before you use desoximetasone topical spray, 0.25%.
- have thinning of the skin (atrophy) at the treatment site
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if desoximetasone topical spray, 0.25% will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if desoximetasone topical spray, 0.25% passes into your breast milk. Do not apply desoximetasone topical spray, 0.25% to your chest area if you are breastfeeding. This will help to prevent your baby from accidentally getting desoximetasone topical spray, 0.25% into the mouth.

Tell your doctor about all the medicines you take including prescription and over-the-counter 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.

What should I avoid while using Desoximetasone Topical Spray, 0.25%?

Desoximetasone Topical Spray, 0.25% is flammable. Avoid heat, flames or smoking while applying desoximetasone topical spray, 0.25% to your skin.

How should I use Desoximetasone Topical Spray, 0.25%?

- Use desoximetasone topical spray, 0.25% exactly as your doctor tells you to use it.
- Apply desoximetasone topical spray, 0.25% two times a day.
- Do not bandage, cover, or wrap the treated skin area.
- Desoximetasone topical spray, 0.25% should be used for the shortest amount of time needed to treat your plaque psoriasis. Tell your doctor if your skin condition is not getting better after 4 weeks of using desoximetasone topical spray, 0.25%. You should not use desoximetasone topical spray, 0.25% for longer than 4 weeks.
- Wash your hands after applying desoximetasone topical spray, 0.25%.
- Safely throw away (discard) any unused desoximetasone topical spray, 0.25% after 30 days.

See the "Instructions for Use" at the end of the Patient Information for detailed information about the right way to apply Desoximetasone Topical Spray, 0.25%.

What are the possible side effects of Desoximetasone Topical Spray, 0.25%?

Desoximetasone topical spray, 0.25% may cause serious side effects, including:

• Desoximetasone topical spray, 0.25% can pass through your skin. Too much desoximetasone topical spray, 0.25% passing through your skin can cause your adrenal glands to stop working. Your doctor may do blood tests to check for adrenal gland problems.

The most common side effects of Desoximetasone Topical Spray, 0.25% include dryness, irritation and itching of skin at the treated site.

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 desoximetasone topical spray, 0.25%. For more information, ask your doctor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov.

You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or visit our website at www.lupinpharmaceuticals.com.

How should I store Desoximetasone Topical Spray, 0.25%?

- Store desoximetasone topical spray, 0.25% at room temperature between 68° to 77°F (20° to 25°C).
- Keep desoximetasone topical spray, 0.25% and all medicines out of the reach of children.
- General information about the safe and effective use of Desoximetasone Topical Spray, 0.25%.
- Do not use desoximetasone topical spray, 0.25% for a condition for which it was not prescribed. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about desoximetasone topical spray, 0.25% that is written for health professionals.

What are the ingredients in Desoximetasone Topical Spray, 0.25%? Active ingredient: desoximetasone USP

Inactive ingredients: butylated hydroxytoluene, diisopropyl adipate, isopropyl alcohol (23.4%), L-menthol, medium-chain triglycerides, mineral oil and sorbitan monooleate.

Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, Maryland 21202 United States

Manufactured by: **Lupin Limited** Pithampur (M.P.) – 454 775 India

Instructions for Use Desoximetasone Topical Spray, 0.25% (des-OX-i-MET-a-sone)

Important information: Desoximetasone topical spray, 0.25% is for use on skin only. Do not get desoximetasone topical spray, 0.25% near or in your mouth, eyes or vagina.

Read the Instructions for Use that comes with desoximetasone topical spray, 0.25% 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.

Parts of Desoximetasone Topical Spray, 0.25% bottle (See Figure A)

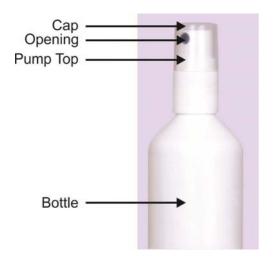


Figure A

How to apply Desoximetasone Topical Spray, 0.25%:

Step 1: Remove the cap from the pump top.

Step 2: Hold the bottle in an upright position while pointing the opening of the pump top in the direction of the affected area. To spray, push down on the pump top. Apply desoximetasone topical spray, 0.25% to the affected area as instructed by your doctor. (See Figure B)

Figure B



Step 3: Spray only enough desoximetasone topical spray, 0.25% to cover the affected area, for example, the elbow (**See Figure C**). Rub in desoximetasone topical spray, 0.25% gently.

Figure C



Repeat Steps 2 and 3 to apply desoximetasone topical spray, 0.25% to other affected areas as instructed by your doctor.

Step 4: After applying desoximetasone topical spray, 0.25%, place the cap back onto the pump top. (**See Figure D**)

Figure D



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

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