Patient Information

Mometasone Furoate (moe—MET—a—sone) Ointment 0.1 %

Important information: Mometasone Furoate Ointment is for use on skin only. Do not use Mometasone Furoate Ointment in your eyes, mouth, or vagina.

What is Mometasone Furoate Ointment?

- Mometasone Furoate Ointment is a prescription medicine used on the skin (topical) for the relief of redness, swelling, heat, pain (inflammation) and itching, caused by certain skin problems in people 2 years of age and older.
 - It is not known if Mometasone Furoate Ointment is safe and effective for use in children under 2 years of age.
 - Mometasone Furoate Ointment should not be used in children under 2 years of age.
 - It is not known if Mometasone Furoate Ointment is safe and effective for use in children longer than 3 weeks.

Do not use Mometasone Furoate Ointment if you are allergic to mometasone furoate or any of the ingredients in Mometasone Furoate Ointment. See the end of this leaflet for a complete list of ingredients in Mometasone Furoate Ointment.

Before using Mometasone Furoate Ointment, tell your healthcare provider about all your medical conditions, including if you:

- have a skin infection at the site to be treated. You may also need medicine to treat the skin infection.
- are pregnant or plan to become pregnant. It is not known if Mometasone Furoate Ointment will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Mometasone Furoate Ointment passes into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take other corticosteroid medicines by mouth or use other products on your skin or scalp that contain corticosteroids.

How should I use Mometasone Furgate Ointment?

- Use Mometasone Furoate Ointment exactly as your healthcare provider tells you to use it.
- Apply a thin film of Mometasone Furoate Ointment to the affected skin area 1 time each day.
- Use Mometasone Furoate Ointment until the affected skin area is improved. Tell your healthcare provider if the treated skin area does not get better after 2 weeks of treatment.
- Do not bandage, cover, or wrap the treated skin area unless your healthcare provider tells you to
- Mometasone Furoate Ointment should not be used to treat diaper rash or redness. Do not apply Mometasone Furoate Ointment in the diaper area if wearing diapers or plastic pants.
- Avoid using Mometasone Furoate Ointment on the face, groin, or underarms (armpits).
- Wash your hands after applying Mometasone Furoate Ointment.

What are the possible side effects of Mometasone Furoate Ointment? Mometasone Furoate Ointment may cause serious side effects, including:

• Mometasone Furoate Ointment can pass through your skin. Too much Mometasone Furoate Ointment passing through your skin can cause your adrenal glands to stop working

properly. Your healthcare provider may do blood tests to check for adrenal gland problems.

- **Vision problems.** Topical corticosteroids may increase your chance of developing vision problems such as cataract and glaucoma. Tell your healthcare provider if you develop blurred vision or other vision problems during treatment with Mometasone Furoate Ointment.
- Skin problems. Skin problems may happen during treatment with Mometasone Furoate Ointment, including allergic reactions (contact dermatitis) and skin infections at the treatment site. Stop using Mometasone Furoate Ointment and tell your healthcare provider if you develop any skin reactions such as pain, tenderness, swelling, or other problems healing during treatment with Mometasone Furoate Ointment.

The most common side effects of Mometasone Furoate Ointment include burning, itching, thinning of the skin (atrophy), tingling, stinging, and boils.

These are not all the possible side effects of Mometasone Furoate Ointment.

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

How should I store Mometasone Furoate Ointment?

Store Mometasone Furoate Ointment at room temperature between 68°F to 77°F (20°C to 25°C).

• Keep Mometasone Furoate Ointment and all medicines out of the reach of children.

General information about the safe and effective use of Mometasone Furoate Ointment.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Mometasone Furoate Ointment for a condition for which it was not prescribed. Do not give Mometasone Furoate Ointment to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Mometasone Furoate Ointment that is written for health professionals.

What are the ingredients in Mometasone Furoate Ointment?

Active ingredient: mometasone furoate

Inactive ingredients: hexylene glycol, phosphoric acid, propylene glycol stearate (55% monoester), purified water, white wax, and white petrolatum.



Manufactured by: TORRENT PHARMACEUTICALS LTD. Pithampur, Dist. Dhar-454 775 (M.P.) INDIA

For:

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This Patient Information has been approved by U.S. Food and Drug Administration.