

Patient Information
DIPROLENE® (DIH-pro-leen)
(augmented betamethasone dipropionate) Ointment

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

What is DIPROLENE Ointment?

DIPROLENE Ointment is a prescription corticosteroid medicine used on the skin (topical) for the relief of redness, swelling, heat, pain (inflammation) and itching, caused by certain skin problems in people 13 years of age and older.

- DIPROLENE Ointment should not be used in children under 13 years of age.

Do not use DIPROLENE Ointment if you are allergic to betamethasone dipropionate or any of the ingredients in DIPROLENE Ointment. See the end of this leaflet for a complete list of ingredients in DIPROLENE Ointment.

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

- have had irritation or other skin reaction to a steroid medicine in the past.
- have thinning of the skin (atrophy) at the treatment site.
- have diabetes.
- have adrenal gland problems.
- have liver problems.
- have cataracts or glaucoma.
- are pregnant or plan to become pregnant. It is not known if DIPROLENE Ointment will harm your unborn baby. If you use DIPROLENE Ointment during pregnancy, use DIPROLENE Ointment on the smallest area of the skin and for the shortest time needed.
- are breastfeeding or plan to breastfeed. It is not known if DIPROLENE Ointment passes into your breast milk. Breastfeeding women should use DIPROLENE Ointment on the smallest area of skin and for the shortest time needed while breastfeeding. Do not apply DIPROLENE Ointment directly to the nipple and areola to avoid contact with your baby.

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 injection or use other products on your skin or scalp that contain corticosteroids.

Do not use other products containing a steroid medicine with DIPROLENE Ointment without talking to your healthcare provider first.

How should I use DIPROLENE Ointment?

- Use DIPROLENE Ointment exactly as your healthcare provider tells you to use it.
- Apply a thin layer (film) of DIPROLENE Ointment to the affected skin area 1 or 2 times each day. Do not use more than 50 grams of DIPROLENE Ointment in 1 week.
- Do not use DIPROLENE Ointment for longer than 2 weeks in a row unless your healthcare provider tells you to.
- Tell your healthcare provider if the treated skin area does not get better after 2 weeks of treatment with DIPROLENE Ointment.
- Do not bandage, cover, or wrap the treated skin area unless your healthcare provider tells you to.
- DIPROLENE Ointment should not be used to treat diaper rash or redness.
- Avoid using DIPROLENE Ointment on the face, groin, or underarms (armpits) or if thinning of the skin (atrophy) is present at the treatment site.
- Wash your hands after applying DIPROLENE Ointment unless you are using the medicine to treat your hands.

What are the possible side effects of DIPROLENE Ointment?

DIPROLENE Ointment may cause serious side effects, including:

- **DIPROLENE Ointment can pass through your skin.** Too much DIPROLENE 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.
- **Cushing's syndrome**, a condition that happens when your body is exposed to too much of the hormone cortisol.
- **High blood sugar** (hyperglycemia).
- **Effects on growth and weight in children.**

- **Vision problems.** Topical corticosteroids including DIPROLENE Ointment may increase your chance of developing cataract(s) and glaucoma. Tell your healthcare provider if you develop blurred vision or other vision problems during treatment with DIPROLENE Ointment.
- **Skin problems.** Skin problems including, allergic reactions (contact dermatitis) may happen during treatment with DIPROLENE Ointment. Stop using DIPROLENE Ointment and tell your healthcare provider if you develop any skin reactions or have problems with healing during treatment with DIPROLENE Ointment.

Your healthcare provider may do certain blood tests to check for side effects.

The most common side effects of DIPROLENE Ointment include redness of the skin, inflamed hair follicles, itching and blistering.

These are not all of the possible side effects of DIPROLENE 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 DIPROLENE Ointment?

- Store DIPROLENE Ointment at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep DIPROLENE Ointment and all medicines out of the reach of children.**

General information about the safe and effective use of DIPROLENE Ointment.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DIPROLENE Ointment for a condition for which it was not prescribed. Do not give DIPROLENE 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 DIPROLENE Ointment that is written for health professionals.

What are the ingredients in DIPROLENE Ointment?

Active ingredient: augmented betamethasone dipropionate

Inactive ingredients: propylene glycol; propylene glycol stearate; white petrolatum; and white wax.

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

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