

Patient Information
DIPROLENE[®] AF (DIH-pro-leen)
(augmented betamethasone dipropionate) Cream

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

What is DIPROLENE AF Cream?

DIPROLENE AF Cream 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 AF Cream should not be used in children under 13 years of age.

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

Before using DIPROLENE AF Cream, 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 AF Cream will harm your unborn baby. If you use DIPROLENE AF Cream during pregnancy, use DIPROLENE AF Cream 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 AF Cream passes into your breast milk. Breastfeeding women should use DIPROLENE AF Cream on the smallest area of the skin and for the shortest time needed. Do not apply DIPROLENE AF Cream 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 AF Cream without talking to your healthcare provider first.

How should I use DIPROLENE AF Cream?

- Use DIPROLENE AF Cream exactly as your healthcare provider tells you to use it.
- Apply a thin layer (film) of DIPROLENE AF Cream to the affected skin area 1 or 2 times each day. Do not use more than 50 grams of DIPROLENE AF Cream in 1 week.
- Do not bandage, cover, or wrap the treated skin area unless your healthcare provider tells you to.
- DIPROLENE AF Cream should not be used to treat diaper rash or redness.
- Avoid using DIPROLENE AF Cream 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 AF Cream unless you are using the medicine to treat your hands.

What are the possible side effects of DIPROLENE AF Cream?

DIPROLENE AF Cream may cause serious side effects, including:

- **DIPROLENE AF Cream can pass through your skin.** Too much DIPROLENE AF Cream 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 AF Cream 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 AF Cream.
- **Skin problems. Skin problems including,** allergic reactions (contact dermatitis) may happen during treatment with DIPROLENE AF Cream. Stop using DIPROLENE AF Cream and tell your healthcare provider if you develop any skin reactions or have problems with healing during treatment with DIPROLENE AF Cream.

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

The most common side effect of DIPROLENE AF Cream in adults includes stinging.

The most common side effects of DIPROLENE AF Cream in children include thinning of the skin (atrophy), tiny red lines or blood vessels showing under the skin (telangiectasia), bruising and shininess. These are not all of the possible side effects of DIPROLENE AF Cream. 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 AF Cream?

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

General information about the safe and effective use of DIPROLENE AF Cream.

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

What are the ingredients in DIPROLENE AF Cream?

Active ingredient: betamethasone dipropionate

Inactive ingredients: carbomer 940; cetareth-30; chlorocresol; cyclomethicone; glyceryl oleate/propylene glycol; propylene glycol; purified water; sodium hydroxide; sorbitol solution; 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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