

Patient Information
ZORYVE® (zor-EEV)
(roflumilast) topical foam, 0.3%

Important information: ZORYVE foam is for use on the skin (topical use) only. Do not use ZORYVE foam in or on your eyes, mouth, or vagina.

What is ZORYVE foam?

ZORYVE foam is a prescription medicine used on the skin (topical) to treat:

- seborrheic dermatitis in adults and children 9 years of age and older.
It is not known if ZORYVE foam is safe and effective in children with seborrheic dermatitis under 9 years of age.
- plaque psoriasis of the scalp and body in adults and children 12 years of age and older.
It is not known if ZORYVE foam is safe and effective in children with plaque psoriasis of the scalp and body under 12 years of age.

Do not use ZORYVE foam if you have certain liver problems.

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

- have liver problems.
- are pregnant or plan to become pregnant. It is not known if ZORYVE foam will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZORYVE foam passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ZORYVE foam.
Breastfeeding women using ZORYVE foam should use it on the smallest area of the skin and for the shortest time needed. Do not apply ZORYVE foam directly to the nipple or areola to avoid contact with your baby. Avoid direct skin contact of treated areas with your baby if ZORYVE foam is applied to your chest.

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

How should I use ZORYVE foam?

- Use ZORYVE foam exactly as your healthcare provider tells you to use it. See the “Instructions for Use” provided with this leaflet for directions about how to apply ZORYVE foam.
- Shake the can of ZORYVE foam before each use.
- Apply a thin layer of ZORYVE foam 1 time a day to the affected areas of your body and scalp when they are not wet. Rub the foam in completely.
- Wash your hands after applying ZORYVE foam. If someone else applies ZORYVE foam for you, they should wash their hands after applying it.

What should I avoid while using ZORYVE foam?

ZORYVE foam is flammable. Avoid fire, flame, and smoking during and right after you apply ZORYVE foam.

What are the possible side effects of ZORYVE foam?

The most common side effects of ZORYVE foam in people treated for seborrheic dermatitis include:

- common cold
- nausea
- headache

The most common side effects of ZORYVE foam in people treated for plaque psoriasis include:

- headache
- diarrhea
- nausea
- common cold

These are not all of the possible side effects of ZORYVE foam.

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 Arcutis Biotherapeutics, Inc. by calling 1-844-692-6729.

How should I store ZORYVE foam?

- Store ZORYVE foam at room temperature between 68°F to 77°F (20°C to 25°C).
- ZORYVE foam is flammable. Keep away from heat and flame.
- The contents in ZORYVE foam are under pressure. **Do not** puncture or burn the can. **Do not** expose the can to heat or store at temperatures above 120°F (49°C).

- **Do not freeze.**
- Store the can upright.

Keep ZORYVE foam and all medicines out of the reach of children.

General Information about the safe and effective use of ZORYVE foam.

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

What are the ingredients in ZORYVE foam?

Active ingredient: roflumilast

Inactive ingredients: cetareth-10 phosphate, cetaryl phosphate, cetostearyl alcohol, diethylene glycol monoethyl ether, hexylene glycol, isopropyl palmitate, methylparaben, propylparaben, purified water, sodium hydroxide, and white petrolatum. Hydrochloric acid may have been added to adjust pH.

Propellants: butane, isobutane, and propane.

Marketed by:

Arcutis Biotherapeutics, Inc.
Westlake Village, CA 91361

For more information on ZORYVE topical foam, call 1-844-692-6729 or visit <http://www.zoryve.com>.

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

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