

**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 under 9 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 it 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.
- Apply a thin layer of ZORYVE foam 1 time a day to the affected areas on skin and scalp when they are not wet. Rub the foam in completely.
- Wash your hands after applying ZORYVE foam. If someone else applies it 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 when applying and right after you apply it.

**What are the possible side effects of ZORYVE foam?**

**The most common side effects include:**

- common cold
- nausea
- headache

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 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 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 you have. It may harm them. You can ask your healthcare provider or pharmacist 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, cetearyl 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, 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.

Issued: 12/2023

v1

**INSTRUCTIONS FOR USE**  
**ZORYVE® (zor-EEV)**  
**(roflumilast) topical foam, 0.3%**

This Instructions for Use contains information on how to apply ZORYVE foam.

Read this Instructions for Use before you start using ZORYVE foam and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment. Use ZORYVE foam exactly as your healthcare provider tells you.

**Important information you need to know before applying ZORYVE foam:**

- **ZORYVE foam is for use on skin only (topical use).** ZORYVE foam is not for use in your eyes, mouth, or vagina.
- **ZORYVE foam is flammable.** Avoid fire, flame, and smoking when applying and right after you apply it.



**Before Applying ZORYVE foam for the first time:**



Gently pull back on the nozzle to break the plastic piece at the base.

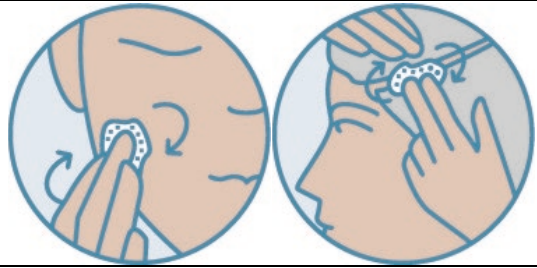
**Applying ZORYVE foam:**

Apply a thin layer of ZORYVE foam **1 time a day** to the affected areas on skin and scalp when they are not wet.

<p><b>Step 1: Shake.</b></p> <ul style="list-style-type: none"><li>• Shake the can well before each use.</li></ul>	 A circular illustration showing a hand holding the white foam canister and shaking it. Motion lines around the canister indicate the shaking action.
<p><b>Step 2: Dispense.</b></p> <ul style="list-style-type: none"><li>• Turn the can upside down and press the nozzle.</li><li>• Dispense a small amount into your hand.</li></ul>	 A circular illustration showing a hand holding the white foam canister upside down. The nozzle is pressed against the palm of another hand, and a small amount of foam is being dispensed.

**Step 3: Apply.**

- Use enough ZORYVE foam to cover all affected areas with a thin layer. Rub the foam in completely.
- If you are treating your scalp, part the hair so that ZORYVE foam can be applied directly to the affected area on the skin.
- Wash your hands after applying.

**Storing 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 to heat or store at temperatures above 120°F (49°C).
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