

Patient Information
ZORYVE® (zor-EEV)
(roflumilast) cream

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

What is ZORYVE cream?

- ZORYVE cream 0.3% is a prescription medicine used on the skin (topical), including in areas with skin folds, to treat plaque psoriasis in adults and children 6 years of age and older.
It is not known if ZORYVE cream 0.3% is safe and effective in children with plaque psoriasis under 6 years of age.
- ZORYVE cream 0.15% is a prescription medicine used on the skin (topical) to treat mild to moderate eczema (atopic dermatitis) in adults and children 6 years of age and older.
It is not known if ZORYVE cream 0.15% is safe and effective in children with mild to moderate eczema (atopic dermatitis) under 6 years of age.
- ZORYVE cream 0.05% is a prescription medicine used on the skin (topical) to treat mild to moderate eczema (atopic dermatitis) in children 2 to 5 years of age.
It is not known if ZORYVE cream 0.05% is safe and effective in children with mild to moderate eczema (atopic dermatitis) under 2 years of age and 6 years of age and older.

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

Before using ZORYVE cream, 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 cream will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZORYVE cream passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ZORYVE cream.
Breastfeeding women using ZORYVE cream should use it on the smallest area of the skin and for the shortest time needed. Do not apply ZORYVE cream directly to the nipple or areola to avoid contact with your baby.

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 cream?

- Use ZORYVE cream exactly as your healthcare provider tells you to use it.
- Apply ZORYVE cream to the affected areas 1 time a day. Rub the cream in completely until you no longer see it on your skin.
- Wash your hands after applying ZORYVE cream. If someone else applies ZORYVE cream for you, they should wash their hands after applying it.

What are the possible side effects of ZORYVE cream?

The most common side effects of ZORYVE cream 0.3% in adults and children 6 years of age and older treated for plaque psoriasis include:

- diarrhea
- headache
- trouble sleeping
- nausea
- application site pain
- upper respiratory tract infections
- urinary tract infections (UTIs)

The most common side effects of ZORYVE cream 0.15% in adults and children 6 years of age and older treated for atopic dermatitis include:

- headache
- nausea
- application site pain
- diarrhea
- vomiting

The most common side effects of ZORYVE cream 0.05% in children 2 to 5 years of age treated for atopic dermatitis include:

- upper respiratory tract infections
- diarrhea
- vomiting
- stuffy or runny nose
- red or swollen eyes (like “pink eye”)
- headache

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

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 cream?

- Store ZORYVE cream at room temperature from 68°F to 77°F (20°C to 25°C).

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

General information about the safe and effective use of ZORYVE cream.

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

What are the ingredients in ZORYVE cream?

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.

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.

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