

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **SEBORRHEIC DERMATITIS**

**PrZORYVE® foam**

#### **Roflumilast**

Read this carefully before you start using ZORYVE foam and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about ZORYVE foam.

#### **What is ZORYVE foam used for?**

ZORYVE foam is used to treat seborrheic dermatitis (a common, red, itchy, flaky skin condition) in patients 9 years of age and older.

ZORYVE foam is not approved in children less than 9 years of age.

#### **How does ZORYVE foam work?**

ZORYVE foam decreases the substances that trigger the skin changes and itchiness of seborrheic dermatitis.

#### **What are the ingredients in ZORYVE foam?**

Medicinal ingredients: roflumilast

Non-medicinal 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, propane.

#### **ZORYVE foam comes in the following dosage forms:**

As a foam containing 3 mg of roflumilast per gram (0.3% w/w) and is delivered from a pressurized can.

#### **Do not use ZORYVE if:**

- You have certain liver problems. You should not use ZORYVE if you have moderate to severe liver problems. Talk to your healthcare professional about any liver problems you may have.
- You are allergic to roflumilast or to any of the other ingredients in ZORYVE.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you use ZORYVE. Talk about any health conditions or problems you may have, including if you:**

- Are pregnant or plan to become pregnant. It is not known if ZORYVE will harm your unborn baby.

**Other warnings you should know about:**

***Breastfeeding:***

Tell your healthcare professional before you use ZORYVE if you are breastfeeding or plan to breastfeed. You should not breastfeed your baby unless your healthcare professional has said that you can. ZORYVE may pass into your breastmilk and harm your baby. Talk to your healthcare professional about the best way to feed your baby during treatment with ZORYVE. If your healthcare professional says that you can breastfeed your baby, use ZORYVE on the smallest area of the skin and for the shortest time needed. Do not apply ZORYVE directly to the nipple or surrounding area. This is so that your baby does not ingest or is exposed to ZORYVE.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.**

**The following may interact with ZORYVE:**

- Erythromycin, used to treat bacterial infections.
- Oral ketoconazole, used to treat fungal infections.
- Fluvoxamine, used to treat certain mental disorders.
- Enoxacin, used to treat bacterial infections.
- Cimetidine, used to treat heartburn and stomach ulcers.

**How to apply ZORYVE foam:**

- Always use ZORYVE foam exactly as your healthcare professional has told you to.
- ZORYVE foam is for use on the skin only. Do not use it in your eyes, mouth, or vagina.
- Rub ZORYVE 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.

**Usual dose:**

Apply ZORYVE foam to affected areas once a day.

**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/or 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>	
<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 of foam into your hand.</li> </ul>	
<p><b>Step 3: APPLY.</b></p> <ul style="list-style-type: none"> <li>Use enough ZORYVE foam to cover all affected areas with a thin layer and rub in completely.</li> <li>If you are treating your scalp, part the hair so that ZORYVE foam can be applied directly to the affected area on the skin.</li> <li>Wash your hands after applying.</li> </ul>	

### Overdose:

If you apply too much ZORYVE, wipe off the excess amount.

If you think you, or a person you are caring for, have used too much ZORYVE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

### Missed Dose:

If you forget to apply ZORYVE, skip the missed dose and go back to your regular dosing schedule the following day.

**What are possible side effects from using ZORYVE foam?**

These are not all the possible side effects you may have when using ZORYVE foam. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- nausea
- common cold
- headache
- trouble sleeping

Side effects reported in clinical trials with roflumilast taken as a pill to treat a condition called chronic obstructive pulmonary disease included:

- fast or irregular heartbeat
- dizziness
- tremor
- anxiety
- depression

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Diarrhea</b> (frequent watery or loose stools)	x		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**Storage:**

Store at 15°C to 30°C, in an upright position. Do not freeze.

Keep out of reach and sight of children.

This product in this pressurized can is very flammable. Do not use in the presence of open flame or spark.

Do not expose to temperatures above 50°C.

Do not puncture or burn the can.

**If you want more information about ZORYVE:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.arcutis.ca](http://www.arcutis.ca), or by calling 1-844-692-6729.

This leaflet was prepared by Arcutis Canada, Inc.

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