

## **PATIENT MEDICATION INFORMATION**

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

**Pr ZORYVE™**

#### **Roflumilast**

Read this carefully before you start using ZORYVE 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.

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

ZORYVE is used on the skin to treat plaque psoriasis in patients 12 years of age and older. This includes areas with skin folds such as under the breasts, underarms, and buttocks.

ZORYVE is not approved in children less than 12 years of age.

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

ZORYVE decreases the substances that trigger the skin changes and itchiness of psoriasis.

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

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.

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

As a cream containing 3 mg of roflumilast per gram (0.3% w/w).

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

- You have certain liver problems. You should not take 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 and 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.
- Oral contraceptives containing gestodene and ethinyl estradiol, used to prevent pregnancy.
- Fluvoxamine, used to treat certain mental disorders.
- Enoxacin, used to treat bacterial infections.
- Cimetidine, used to treat heartburn and stomach ulcers.

**How to take ZORYVE:**

- Always use ZORYVE exactly as your healthcare professional has told you to.
- ZORYVE is for use on the skin only. Do not use it in your eyes, mouth, or vagina.
- Rub ZORYVE in completely until you no longer see it on your skin.
- Wash your hands after applying ZORYVE, unless you are treating your hands.
- If someone else applies ZORYVE for you, they should wash their hands after applying it.

**Usual dose:**

Apply ZORYVE to affected areas once a day.

**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?**

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

Side effects may include:

- headache
- diarrhea
- trouble sleeping
- pain at the cream application site
- weight loss

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

<b>Serious side effects and what to do about them</b>			
<b>Symptom / effect</b>	<b>Talk to your healthcare professional</b>		<b>Stop taking drug and get immediate medical help</b>
	<b>Only if severe</b>	<b>In all cases</b>	
<b>COMMON</b>			
<b>Diarrhea</b> (frequent watery or loose stools)	x		
<b>Upper respiratory tract infection</b> (infection of your nose, sinuses, and throat): cough, runny or stuffy nose, sore throat	x		
<b>Urinary tract infection</b> (infection in urinary system including kidneys, ureters, bladder, and urethra): pain or burning sensation while urinating, frequent urination, blood in urine, pain in the pelvis, strong-smelling urine, cloudy urine		x	
<b>Nausea</b> (feeling sick to your stomach)	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.

Keep out of reach and sight of children.

### **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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