

<p><b>Patient Information</b>  <b>ZORYVE™ (zor-EEV)</b>  <b>(roflumilast) cream</b></p>
<p><b>Important information: ZORYVE is for use on the skin (topical use) only.</b> Do not use ZORYVE in or on your eyes, mouth, or vagina.</p>
<p><b>What is ZORYVE?</b>  ZORYVE is a prescription medicine used on the skin (topical), including in areas with skin folds, to treat plaque psoriasis in people 12 years of age and older.  It is not known if ZORYVE is safe and effective in children under 12 years of age.</p>
<p><b>Do not use ZORYVE if you have certain liver problems.</b></p>
<p><b>Before using ZORYVE, tell your healthcare provider about all of your medical conditions, including if you:</b></p> <ul style="list-style-type: none"> <li>• have liver problems</li> <li>• are pregnant or plan to become pregnant. It is not known if ZORYVE will harm your unborn baby.</li> <li>• are breastfeeding or plan to breastfeed. It is not known if ZORYVE passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with ZORYVE.  Breastfeeding women using ZORYVE should use ZORYVE on the smallest area of the skin and for the shortest time needed. Do not apply ZORYVE directly to the nipple and areola to avoid contact with your baby.</li> </ul> <p><b>Tell your healthcare provider about the medicines you take,</b> including prescription and over-the-counter medicines, vitamins, and herbal supplements.</p>
<p><b>How should I use ZORYVE?</b></p> <ul style="list-style-type: none"> <li>• Use ZORYVE exactly as your healthcare provider tells you to use it.</li> <li>• Apply ZORYVE to the affected areas 1 time a day. Rub the cream in completely until you no longer see it on your skin.</li> <li>• Wash your hands after applying ZORYVE, unless your hands are being treated. If someone else applies ZORYVE for you, they should wash their hands after applying ZORYVE.</li> </ul>
<p><b>What are the possible side effects of ZORYVE?</b>  <b>The most common side effects of ZORYVE include:</b></p> <ul style="list-style-type: none"> <li>• diarrhea</li> <li>• headache</li> <li>• trouble sleeping</li> <li>• nausea</li> <li>• application site pain</li> <li>• upper respiratory tract infections</li> <li>• urinary tract infections (UTIs)</li> </ul> <p>These are not all of the possible side effects of ZORYVE.  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.</p>
<p><b>How should I store ZORYVE?</b></p> <ul style="list-style-type: none"> <li>• Store ZORYVE at room temperature from 68°F to 77°F (20°C to 25°C).</li> </ul> <p><b>Keep ZORYVE and all medicines out of the reach of children.</b></p>
<p><b>General Information about the safe and effective use of ZORYVE.</b>  Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ZORYVE for a condition for which it was not prescribed. Do not give ZORYVE 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 that is written for health professionals.</p>
<p><b>What are the ingredients in ZORYVE?</b>  <b>Active ingredient:</b> roflumilast  <b>Inactive ingredients:</b> 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.</p>

**Marketed by:** Arcutis Biotherapeutics, Inc.  
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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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