

## 16 HOW SUPPLIED/STORAGE AND HANDLING

ACZONE (dapsone) Gel, 5%, is supplied in the following size tubes:

Professional Sample  
5 % NDC XXXX-XXXX-XX                      Product Code 500503  
3 gram laminate tube

Commercially Available as:  
5 % NDC XXXX-XXXX-XX                      Product Code 500530  
30 gram laminate tube

### KEEP OUT OF THE REACH OF CHILDREN LESS THAN 12 YEARS OLD.

Storage conditions:

Store at controlled room temperature, 20-25°C (68-76°F), excursions permitted to 15-30°C (59-86°F). Protect from freezing.

## 17 PATIENT COUNSELING INFORMATION

See FDA Approved-Patient Labeling (17.2)

### 17.1 Information for Patients

1. Patients should use ACZONE Gel, 5%, as directed by the physician. ACZONE Gel, 5%, is for external topical use only. ACZONE Gel, 5%, is not for oral, ophthalmic or intravaginal use.
2. Patients should not use this medication for any disorder other than that for which it was prescribed.
3. Patients should report any signs of adverse reactions to their physician.
4. Protect ACZONE Gel, 5%, from freezing.
5. See Patient Labeling for additional information on safety, efficacy, general use, and storage of ACZONE Gel, 5%.

### 17.2 FDA-Approved Patient Labeling

ACZONE™ (dapsone) Gel 5%

Read this important information before you start using ACZONE (AK-zōn) Gel and each time you refill your prescription. There may be new information that you need to know. This summary is not meant to take the place of your doctor's advice. If you have any questions or want more information about ACZONE Gel, ask your doctor or pharmacist.

#### **What is ACZONE Gel?**

ACZONE Gel is a prescription medicine used on your skin (topical) to treat acne in people 12 years and older.

ACZONE Gel has not been studied in children under 12 years of age.

#### **Who should not use ACZONE Gel?**

Do not use ACZONE Gel if you are allergic to any of the ingredients in ACZONE Gel or if you are younger than 12 years of age.

**Active ingredient:** dapsone.

**Inactive ingredients:** Carbomer 980, diethylene glycol monoethyl ether (DGME), methylparaben, sodium hydroxide, and purified water.

#### **What should I tell my doctor before using ACZONE Gel?**

**Tell your doctor about all of your medical conditions, including if you:**

- **are pregnant or planning to become pregnant.** It is not known if ACZONE Gel may harm your unborn baby. **You and your doctor will need to decide if ACZONE is right for you.**
- **are breastfeeding.** ACZONE Gel passes into your milk and may harm your baby. You should choose either to use ACZONE Gel, or breastfeed, but not both. Talk to your doctor about the best way to feed your baby while using ACZONE Gel.
- **have glucose-6-phosphate dehydrogenase deficiency.**

**Tell your doctor about all the medicines you are taking including prescription and nonprescription medicines, vitamins and herbal supplements.** Especially, tell your doctor if you are using any other medicines applied to the skin, such as acne medicines with benzoyl peroxide.

#### **How do I use ACZONE Gel?**

- Use ACZONE Gel exactly as prescribed by your doctor. ACZONE Gel is usually used on your affected skin twice a day, once in the morning and once in the evening.
- Wash the areas of your skin where you will apply ACZONE Gel. Gently pat your skin dry with a clean towel.
- Apply a thin layer of ACZONE Gel to the areas of your skin that have acne. A pea-sized amount of ACZONE Gel will usually be enough.
- Rub the medicine in gently and completely
- Make sure to put the cap back on the ACZONE Gel tube. Close it tightly.
- Wash your hands after applying ACZONE Gel.
- Keep ACZONE Gel away from your mouth and eyes. Do not swallow ACZONE Gel. If you swallow ACZONE Gel, call your doctor or poison control center right away.
- If your acne does not get better after using ACZONE Gel for 12 weeks, talk to your doctor about other treatments for acne.

#### **What are the possible side effects of ACZONE Gel?**

Like all medicines, ACZONE Gel can cause some side effects. The most common side effects of ACZONE Gel are dryness, redness, oiliness and peeling of the skin being treated.

**When the active ingredient of ACZONE Gel (called dapsone) is taken orally as a pill, it has been related to the abnormal breakdown of red blood cells (hemolytic anemia). If you have glucose-6-phosphate dehydrogenase deficiency, you may have a greater risk for lowering your hemoglobin level. However, using ACZONE Gel on the skin is not expected to put enough dapsone in the blood to cause clinical symptoms of hemolytic anemia. You are advised to be alert for signs and symptoms suggestive of this type of anemia (sudden onset of: back pain, breathlessness, tiredness/weakness with daily activities, dark-**

brown urine, high fever and yellow or pale skin). If you experience these signs and symptoms, stop use and call your doctor immediately.

Use of benzoyl peroxide together with ACZONE Gel at the same time may cause your skin to temporarily turn yellow or orange at the site of application.

This is not a complete list of all the possible side effects. Call your doctor if you have any side effects that do not go away or bother you. If you have any questions, ask your doctor or pharmacist.

***How should I store ACZONE Gel?***

Store ACZONE Gel at room temperature 68 to 76°F. Do not freeze ACZONE Gel.

Keep ACZONE Gel out of the reach of children less than 12 years of age.

***Where can I find more information about ACZONE Gel?***

If you have any questions or want more information about ACZONE Gel, ask your doctor or pharmacist. Your doctor or pharmacist can also give you a copy of the ACZONE Gel Package Insert written for health professionals. Ask them to explain anything you do not understand.

You may call 1-800-[ACZONE Call Number] to obtain more information about ACZONE™ Gel.

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**ACZONE™ (dapsone) Gel, 5%**

Manufactured by Tolmar, Inc. Fort Collins, CO 80526 for QLT, USA, Inc., Fort Collins, CO 80525