HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ACZONE® Gel, 5% safely and effectively. See full prescribing information for ACZONE® Gel, 5%.

ACZONE® (dapsone) Gel, 5%, for topical use only
Initial U.S. Approval: 1955

----------RECENT MAJOR CHANGES----------
Warnings and Precautions, Methemoglobinemia (5.1) 7/2015

----------INDICATIONS AND USAGE----------
ACZONE® Gel is indicated for the topical treatment of acne vulgaris (1).

----------DOSAGE AND ADMINISTRATION----------
- Apply twice daily (2).
- Apply approximately a pea-sized amount of **ACZONE®** Gel, 5%, in a thin layer to the acne affected area (2).
- If there is no improvement after 12 weeks, treatment with **ACZONE®** Gel, 5%, should be reassessed (2).
- For topical use only. Not for oral, ophthalmic, or intravaginal use (2).

----------DOSAGE FORMS AND STRENGTHS----------
Gel, 5% (3).

----------CONTRAINDICATIONS----------
None (4).

----------WARNINGS AND PRECAUTIONS----------
- Methemoglobinemia: Cases of methemoglobinemia have been reported. Discontinue **ACZONE®** gel if signs of methemoglobinemia occur (5.1).
- Hematologic Effects: Some subjects with G6PD deficiency using **ACZONE®** Gel developed laboratory changes suggestive of hemolysis. (5.2)(8.6).

----------ADVERSE REACTIONS----------
Most common adverse reactions (incidence ≥ 10%) are oiliness/peeling, dryness and erythema at the application site (6).

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-433-8871 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch.*

----------DRUG INTERACTIONS----------
- Trimethoprim/sulfamethoxazole (TMP/SMX) increases the level of dapsone and its metabolites (7.1).
- Topical benzoyl peroxide used at the same time as **ACZONE®** may result in temporary local yellow or orange skin discoloration (7.2).

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 7/2015

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

ACZONE® Gel, 5%, is indicated for the topical treatment of acne vulgaris.

2 DOSAGE AND ADMINISTRATION

For topical use only. Not for oral, ophthalmic, or intravaginal use.

After the skin is gently washed and patted dry, apply approximately a pea-sized amount of **ACZONE**® Gel, 5%, in a thin layer to the acne affected areas twice daily. Rub in **ACZONE**® Gel, 5%, gently and completely. **ACZONE**® Gel, 5%, is gritty with visible drug substance particles. Wash hands after application of **ACZONE**® Gel, 5%.

If there is no improvement after 12 weeks, treatment with **ACZONE**® Gel, 5%, should be reassessed.

3 DOSAGE FORMS AND STRENGTHS

Gel, 5%. Each gram of **ACZONE**® gel contains 50 mg of dapsone in a white to pale yellow gel.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Methemoglobinemia

Cases of methemoglobinemia, with resultant hospitalization, have been reported postmarketing in association with **ACZONE**® Gel, 5% treatment. Patients with glucose-6-phosphate dehydrogenase deficiency or congenital or idiopathic methemoglobinemia are more susceptible to drug-induced methemoglobinemia. Avoid use of **ACZONE**® Gel, 5% in those patients with congenital or idiopathic methemoglobinemia.

Signs and symptoms of methemoglobinemia may be delayed some hours after exposure. Initial signs and symptoms of methemoglobinemia are characterized by a slate grey cyanosis seen in, e.g., buccal mucous membranes, lips and nail beds. Advise patients to discontinue **ACZONE**® Gel, 5% and seek immediate medical attention in the event of cyanosis.

Dapsone can cause elevated methemoglobin levels particularly in conjunction with methemoglobin-inducing agents.

5.2 Hematologic Effects

Oral dapsone treatment has produced dose-related hemolysis and hemolytic anemia. Individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency are more prone to hemolysis with the use of certain drugs. G6PD deficiency is most prevalent in populations of African, South Asian, Middle Eastern, and Mediterranean ancestry.

Some subjects with G6PD deficiency using **ACZONE**® Gel developed laboratory changes suggestive of hemolysis. There was no evidence of clinically relevant hemolysis or anemia in patients treated with **ACZONE**® Gel, 5%, including patients who were G6PD deficient.

Discontinue **ACZONE**® Gel, 5%, if signs and symptoms suggestive of hemolytic anemia occur. Avoid use of **ACZONE**® Gel, 5% in patients who are taking oral dapsone or antimalarial medications because of the potential for hemolytic reactions. Combination of **ACZONE**® Gel, 5%, with trimethoprim/sulfamethoxazole (TMP/SMX) may increase the likelihood of hemolysis in patients with G6PD deficiency.

5.3 Peripheral Neuropathy

Peripheral neuropathy (motor loss and muscle weakness) has been reported with oral dapsone treatment. No events of peripheral neuropathy were observed in clinical trials with topical **ACZONE®** Gel, 5% treatment.

5.4 Skin

Skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria) have been reported with oral dapsone treatment. These types of skin reactions were not observed in clinical trials with topical **ACZONE®** Gel, 5% treatment.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Serious adverse reactions reported in patients treated with **ACZONE®** Gel, 5%, during clinical trials included but were not limited to the following:

- Nervous system/Psychiatric – Suicide attempt, tonic clonic movements.
- Gastrointestinal – Abdominal pain, severe vomiting, pancreatitis.
- Other – Severe pharyngitis

In the clinical trials, a total of 12 out of 4032 patients were reported to have depression (3 of 1660 treated with vehicle and 9 of 2372 treated with **ACZONE®** Gel, 5%). Psychosis was reported in 2 of 2372 patients treated with **ACZONE®** Gel, 5%, and in 0 of 1660 patients treated with vehicle.

Combined contact sensitization/irritation studies with **ACZONE®** Gel, 5%, in 253 healthy subjects resulted in at least 3 subjects with moderate erythema. **ACZONE®** Gel, 5%, did not induce phototoxicity or photoallergy in human dermal safety studies.

ACZONE® Gel, 5%, was evaluated for 12 weeks in four controlled studies for local cutaneous events in 1819 patients. The most common events reported from these studies include oiliness/peeling, dryness, and erythema. These data are shown by severity in Table 1 below.

Table 1 – Application Site Adverse Reactions by Maximum Severity

	ACZONE® (N=1819)			Vehicle (N=1660)		
Application Site Event	Mild	Moderate	Severe	Mild	Moderate	Severe
Erythema	9%	5%	<1%	9%	6%	<1%
Dryness	14%	3%	<1%	14%	4%	<1%
Oiliness/Peeling	13%	6%	<1%	15%	6%	<1%

The adverse reactions occurring in at least 1% of patients in either arm in the four vehicle controlled studies are presented in Table 2.

Table 2 – Adverse Reactions Occurring in at Least 1% of Patients

	ACZONE® N=1819	Vehicle N=1660
Application Site Reaction NOS	18%	20%
Application Site Dryness	16%	17%
Application Site Erythema	13%	14%
Application Site Burning	1%	2%
Application Site Pruritus	1%	1%
Pyrexia	1%	1%
Nasopharyngitis	5%	6%
Upper Respiratory Tract Inf. NOS	3%	3%
Sinusitis NOS	2%	1%
Influenza	1%	1%
Pharyngitis	2%	2%
Cough	2%	2%
Joint Sprain	1%	1%
Headache NOS	4%	4%

NOS = Not otherwise specified

One patient treated with **ACZONE®** Gel in the clinical trials had facial swelling which led to discontinuation of medication.

In addition, 486 patients were evaluated in a 12 month safety study. The adverse event profile in this study was consistent with that observed in the vehicle-controlled studies.

6.2 Experience with Oral Use of Dapsone

Although not observed in the clinical trials with **ACZONE®** Gel (topical dapsone) serious adverse reactions have been reported with oral use of dapsone, including agranulocytosis, hemolytic anemia, peripheral neuropathy (motor loss and muscle weakness), and skin reactions (toxic epidermal necrolysis, erythema multiforme, morbilliform and scarlatiniform reactions, bullous and exfoliative dermatitis, erythema nodosum, and urticaria).

6.3 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of **ACZONE®** Gel, 5%. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Methemoglobinemia has been identified during postmarketing use of **ACZONE®** Gel, 5% *[see Warnings and Precautions (5.1)]*.

7 DRUG INTERACTIONS

7.1 Trimethoprim-Sulfamethoxazole

A drug-drug interaction study evaluated the effect of the use of **ACZONE®** Gel, 5%, in combination with double strength (160 mg/800 mg) trimethoprim-sulfamethoxazole (TMP/SMX). During co-administration, systemic levels of TMP and SMX were essentially unchanged. However, levels of dapsone and its metabolites increased in the presence of TMP/SMX. Systemic exposure (AUC_{0-12}) of dapsone and N-acetyl-dapsone (NAD) were increased by about 40% and 20% respectively in the presence of TMP/SMX. Notably, systemic exposure (AUC_{0-12}) of dapsone hydroxylamine (DHA) was more than doubled in the presence of TMP/SMX. Exposure from the proposed topical dose is about 1% of that from the 100 mg oral dose, even when co-administered with TMP/SMX.

7.2 Topical Benzoyl Peroxide

Topical application of **ACZONE®** Gel followed by benzoyl peroxide in subjects with acne vulgaris resulted in a temporary local yellow or orange discoloration of the skin and facial hair (reported by 7 out of 95 subjects in a clinical study) with resolution in 4 to 57 days.

7.3 Drug Interactions with Oral Dapsone

Certain concomitant medications (such as rifampin, anticonvulsants, St. John's wort) may increase the formation of dapsone hydroxylamine, a metabolite of dapsone associated with hemolysis. With oral dapsone treatment, folic acid antagonists such as pyrimethamine have been noted to possibly increase the likelihood of hematologic reactions.

7.4 Concomitant Use with Drugs that Induce Methemoglobinemia

Concomitant use of **ACZONE®** with drugs that induce methemoglobinemia such as sulfonamides, acetaminophen, acetanilide, aniline dyes, benzocaine, chloroquine, dapsone, naphthalene, nitrates and nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine, and quinine may increase the risk for developing methemoglobinemia *[see Warnings and Precautions (5.1)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects: Pregnancy Category C

There are no adequate and well controlled studies in pregnant women. Dapsone has been shown to have an embryocidal effect in rats and rabbits when administered orally in doses of 75 mg/kg/day and 150 mg/kg/day (approximately 800 and 500 times the systemic exposure observed in human females as a result of use of the maximum recommended topical dose, based on AUC comparisons), respectively. These effects were probably secondary to maternal toxicity. **ACZONE®** Gel, 5%, should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

Although systemic absorption of dapsone following topical application of **ACZONE®** Gel, 5%, is minimal relative to oral dapsone administration, it is known that dapsone is excreted in human milk. Because of the potential for oral dapsone to cause adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue **ACZONE®** Gel, 5%, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

Safety and efficacy was evaluated in 1169 children aged 12-17 years old treated with **ACZONE®** Gel, 5%, in the clinical studies. The adverse event rate for **ACZONE®** Gel, 5%, was similar to the vehicle control group. Safety and efficacy was not studied in pediatric patients less than 12 years of age, therefore **ACZONE®** Gel, 5%, is not recommended for use in this age group.

8.5 Geriatric Use

Clinical studies of **ACZONE®** Gel, 5%, did not include sufficient number of patients aged 65 and over to determine whether they respond differently from younger patients.

8.6 G6PD Deficiency

ACZONE® Gel, 5% and vehicle were evaluated in a randomized, double-blind, cross-over design clinical study of 64 patients with G6PD deficiency and acne vulgaris. Subjects were Black (88%), Asian (6%), Hispanic (2%) or of other racial origin (5%). Blood samples were taken at Baseline, Week 2, and Week 12 during both vehicle and **ACZONE®** Gel, 5% treatment periods. There were 56 out of 64 subjects who had a Week 2 blood draw and applied at least 50% of treatment applications. Table 3 contains results from testing of relevant hematology parameters for these two treatment periods. **ACZONE®** Gel was associated with a 0.32 g/dL drop in hemoglobin after two weeks of treatment, but hemoglobin levels generally returned to baseline levels at Week 12.

Table 3 – Mean Hemoglobin, Bilirubin, and Reticulocyte Levels in Acne Subjects with G6PD Deficiency in ACZONE®/Vehicle Cross-Over Study

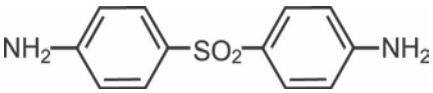
		ACZONE®		Vehicle	
		N	Mean	N	Mean
Hemoglobin (g/dL)	Pre-treatment	53	13.44	56	13.36
	2 weeks	53	13.12	55	13.34
	12 weeks	50	13.42	50	13.37
Bilirubin (mg/dL)	Pre-treatment	54	0.58	56	0.55
	2 weeks	53	0.65	55	0.56
	12 weeks	50	0.61	50	0.62
Reticulocytes (%)	Pre-treatment	53	1.30	55	1.34
	2 weeks	53	1.51	55	1.34
	12 weeks	50	1.48	50	1.41

There were no changes from baseline in haptoglobin or lactate dehydrogenase during **ACZONE®** or vehicle treatment at either the 2-week or 12-week time point.

The proportion of subjects who experienced decreases in hemoglobin ≥1 g/dL was similar between **ACZONE®** Gel, 5% and vehicle treatment (8 of 58 subjects had such decreases during **ACZONE®** treatment compared to 7 of 56 subjects during vehicle treatment among subjects with at least one on-treatment hemoglobin assessment). Subgroups based on gender, race, or G6PD enzyme activity did not display any differences in laboratory results from the overall study group. There was no evidence of clinically significant hemolytic anemia in this study. Some of these subjects developed laboratory changes suggestive of hemolysis.

11 DESCRIPTION

ACZONE® Gel, 5%, contains dapsone, a sulfone, in an aqueous gel base for topical dermatologic use. **ACZONE®** Gel, 5% is a gritty translucent material with visible drug substance particles. Chemically, dapsone has an empirical formula of $C_{12}H_{12}N_2O_2S$. It is a white, odorless crystalline powder that has a molecular weight of 248. Dapsone's chemical name is 4,4'-diaminodiphenylsulfone and its structural formula is:



Each gram of **ACZONE®** Gel, 5%, contains 50 mg of dapsone, USP, in a gel of carbomer homopolymer type C; diethylene glycol monoethyl ether, NF; methylparaben, NF; sodium hydroxide, NF; and purified water, USP.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of dapsone gel in treating acne vulgaris is not known.

12.3 Pharmacokinetics

An open-label study compared the pharmacokinetics of dapsone after **ACZONE®** Gel, 5%, (110 ± 60 mg/day) was applied twice daily (~BSA 22.5%) for 14 days (n=18) with a single 100 mg dose of oral dapsone administered to a subgroup of patients (n=10) in a crossover design. On Day 14 the mean dapsone $AUC_{0\text{-}24h}$ was 415 ± 224 ng•h/mL for **ACZONE®** Gel, 5%, whereas following a single 100 mg dose of oral dapsone the $AUC_{0\text{-}infinity}$ was 52,641 ± 36,223 ng•h/mL. Exposure after the oral dose of 100 mg dapsone was approximately 100 times greater than after the topical **ACZONE®** Gel, 5% dose, twice a day.

In a long-term safety study of **ACZONE®** Gel, 5% treatment, periodic blood samples were collected up to 12 months to determine systemic exposure of dapsone and its metabolites in approximately 500 patients. Based on the measurable dapsone concentrations from 408 patients (M=192, F=216), obtained at month 3, neither gender, nor race appeared to affect the pharmacokinetics of dapsone. Similarly, dapsone exposures were approximately the same between the age groups of 12-15 years (N=155) and those greater than or equal to 16 years (N=253). There was no evidence of increasing systemic exposure to dapsone over the study year in these patients.

12.4 Microbiology

In Vivo Activity: No microbiology or immunology studies were conducted during dapsone gel clinical trials.

Drug Resistance: No dapsone resistance studies were conducted during dapsone gel clinical trials. Because no microbiology studies were done, there are no data available as to whether dapsone treatment may have resulted in decreased susceptibility of *Propionibacterium acnes*, an organism associated with acne, to other antimicrobials that may be used to treat acne. Therapeutic resistance to dapsone has been reported for *Mycobacterium leprae*, when patients have been treated with oral dapsone.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Dapsone was not mutagenic in a bacterial reverse mutation assay (Ames test) using *S. typhimurium* and *E. coli*, with and without metabolic activation and was negative in a micronucleus assay conducted in mice. Dapsone increased both numerical and structural aberrations in a chromosome aberration assay conducted with Chinese hamster ovary (CHO) cells.

Dapsone was not carcinogenic to rats when orally administered to females for 92 weeks or males for 100 weeks at dose levels up to 15 mg/kg/day (approximately 160 times the systemic exposure observed in human males and 300 times the systemic exposure observed in human females as a result of use of the maximum recommended topical dose, based on AUC comparisons).

No evidence of potential to induce carcinogenicity was obtained in a dermal study in which dapsone gel was topically applied to Tg.AC transgenic mice for approximately 26 weeks. Dapsone concentrations of 3%, 5%, and 10% were evaluated; 3% material was judged to be the maximum tolerated dosage.

ACZONE® Gel, 5%, did not increase the rate of formation of ultraviolet light-induced skin tumors when topically applied to hairless mice in a 12-month photocarcinogenicity study.

The effects of dapsone on fertility and general reproduction performance were assessed in male and female rats following oral (gavage) dosing. Dapsone reduced sperm motility at dosages of 3 mg/kg/day or greater (approximately 17 times the systemic exposure observed in human males as a result of use of the maximum recommended topical dose, based on AUC comparisons). The mean numbers of embryo implantations and viable embryos were significantly reduced in untreated females mated with males that had been dosed at 12 mg/kg/day or greater (approximately 70 times the systemic exposure observed in human males as a result of use of the maximum recommended topical dose, based on AUC comparisons), presumably due to reduced numbers or effectiveness of sperm, indicating impairment of fertility. Dapsone had no effect on male fertility at dosages of 2 mg/kg/day or less (approximately 13 times the systemic exposure observed in human males as a result

of use of the maximum recommended topical dose, based on AUC comparisons). When administered to female rats at a dosage of 75 mg/kg/day (approximately 800 times the systemic exposure observed in human females as a result of use of the maximum recommended topical dose, based on AUC comparisons) for 15 days prior to mating and for 17 days thereafter, dapsone reduced the mean number of implantations, increased the mean early resorption rate, and reduced the mean litter size. These effects were probably secondary to maternal toxicity.

Dapsone was assessed for effects on perinatal/postnatal pup development and postnatal maternal behavior and function in a study in which dapsone was orally administered to female rats daily beginning on the seventh day of gestation and continuing until the twenty-seventh day postpartum. Maternal toxicity (decreased body weight and food consumption) and developmental effects (increase in stillborn pups and decreased pup weight) were seen at a dapsone dose of 30 mg/kg/day (approximately 500 times the systemic exposure observed in human females as a result of use of the maximum recommended topical dose, based on AUC comparisons). No effects were observed on the viability, physical development, behavior, learning ability, or reproductive function of surviving pups.

14 CLINICAL STUDIES

Two randomized, double-blind, vehicle-controlled, clinical studies were conducted to evaluate **ACZONE®** Gel, 5%, for the treatment of patients with acne vulgaris (N=1475 and 1525). The studies were designed to enroll patients 12 years of age and older with 20 to 50 inflammatory and 20 to 100 non-inflammatory lesions at baseline. In these studies patients applied either **ACZONE®** Gel, 5%, or vehicle control twice daily for up to 12 weeks. Efficacy was evaluated in terms of success on the Global Acne Assessment Score (no or minimal acne) and in the percent reduction in inflammatory, non-inflammatory, and total lesions.

The Global Acne Assessment Score was a 5-point scale as follows:

0 None: no evidence of facial acne vulgaris
1 Minimal: few non-inflammatory lesions (comedones) are present; a few inflammatory lesions (papules/pustules) may be present
2 Mild: several to many non-inflammatory lesions (comedones) are present; a few inflammatory lesions (papules/pustules) are present
3 Moderate: many non-inflammatory (comedones) and inflammatory lesions (papules/pustules) are present; no nodulo-cystic lesions are allowed
4 Severe: significant degree of inflammatory disease; papules/pustules are a predominant feature; a few nodulo-cystic lesions may be present; comedones may be present.

The success rates on the Global Acne Assessment Score (no or minimal acne) at Week 12 are presented in Table 4.

Table 4 - Success (No or Minimal Acne) on the Global Acne Assessment Score at Week 12

	Study 1*		Study 2*	
	ACZONE® N=699	Vehicle N=687	**ACZONE®** N=729	Vehicle N=738
Subjects with No or Minimal Acne	291 (42%)	223 (32%)	253 (35%)	206 (28%)

*Analysis excludes subjects classified with minimal acne at baseline

Table 5 presents the mean percent reduction in inflammatory, non-inflammatory, and total lesions from baseline to Week 12.

Table 5 - Percent Reduction in Lesions from Baseline to Week 12

	Study 1		Study 2	
	ACZONE® N=745	Vehicle N=740	**ACZONE®** N=761	Vehicle N=764
Inflammatory	46%	42%	48%	40%
Non-Inflammatory	31%	24%	30%	21%
Total	38%	32%	37%	29%

The clinical studies enrolled about equal proportions of male and female subjects. Female patients tended to have greater percent reductions in lesions and greater success on the Global Acne Assessment Score than males. The breakdown by race in the clinical studies was about 73% Caucasian, 14% Black, 9% Hispanic, and 2% Asian. Efficacy results were similar across the racial subgroups.

16 HOW SUPPLIED/STORAGE AND HANDLING

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

NDC 0023-3670-30
30 gram laminate tube

NDC 0023-3670-60
60 gram laminate tube

NDC 0023-3670-90
90 gram laminate tube

Store **ACZONE®** gel at controlled room temperature, 20°-25°C (68°-77°F), excursions permitted to 15°-30ºC (59°-86ºF). Protect from freezing.

17 PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Patient Information)

- Advise patient to seek immediate medical attention for cyanosis *[see Warnings and Precautions (5.1)]*.
- Advise patient to 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.
- Advise patients to report any signs of adverse reactions to their physician.
- Protect **ACZONE®** Gel, 5%, from freezing.
- See Patient Information for additional information on safety, efficacy, general use, and storage of **ACZONE®** Gel, 5%.

Made in the U.S.A.

ALLERGAN

PATIENT INFORMATION

ACZONE® (AK-zōn) (dapsone) Gel, 5%

Important: For use on skin only (topical use). Do not use ACZONE® Gel, 5% in or on your mouth, eyes, or vagina.

What is ACZONE® Gel, 5%?

ACZONE® Gel, 5% is a prescription medicine used on your skin (topical) to treat acne vulgaris.
ACZONE® Gel has not been studied in children under 12 years of age.

Before using ACZONE® Gel, 5%, tell your doctor about all of your medical conditions, including if you:

- Have glucose-6-phosphate dehydrogenase deficiency (G6PD)
- Have higher than normal levels of methemoglobin in your blood (methemoglobinemia)
- Are pregnant or plan to become pregnant. It is not known if ACZONE® Gel, 5 % will harm your unborn baby.
- Are breastfeeding or plan to breastfeed. ACZONE® Gel, 5% can pass into your breast milk and may harm your baby. You and your doctor should decide if you will use ACZONE® Gel, 5% or breastfeed. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your doctor if you are using acne medicines that contain benzoyl peroxide. Use of benzoyl peroxide with ACZONE® Gel, 5% at the same time may cause your skin or facial hair to temporarily turn yellow or orange at the site of application.

How should I use ACZONE® Gel, 5%?

- Use ACZONE® Gel, 5% exactly as your doctor tells you.
- Apply ACZONE® Gel, 5% twice a day.
- Gently wash and pat dry the areas of your skin where you will apply ACZONE® Gel, 5%.
- Apply a pea-sized amount of ACZONE® Gel, 5% in a thin layer to the areas of your skin that have acne.
- Rub ACZONE® Gel, 5% in gently and completely. It may feel gritty and you may see particles in the gel.
- Make sure to put the cap back on the ACZONE® Gel tube. Close it tightly.
- Wash your hands after applying ACZONE® Gel, 5%.
- 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, 5% for 12 weeks, talk to your doctor about continuing treatment.

What are the possible side effects of ACZONE® Gel, 5%?

ACZONE® Gel, 5% may cause serious side effects, including:

- **Decrease of oxygen in your blood caused by a certain type of abnormal red blood cell (methemoglobinemia).** Stop using ACZONE® Gel, 5% and get medical help right away if your lips, nail beds, or the inside of your mouth turns grey or blue.
- **Breakdown of red blood cells (hemolytic anemia).** Some people with G6PD deficiency using ACZONE® Gel, 5% have developed mild hemolytic anemia. Stop using ACZONE® Gel, 5% and tell your doctor right away if you get any of the following signs and symptoms:
  - o back pain
  - o dark brown urine
  - o shortness of breath
  - o fever
  - o tiredness or weakness
  - o yellow or pale skin

The most common side effects of ACZONE® Gel, 5% include oiliness, peeling, dryness, and redness of the skin being treated.

These are not all of the possible side effects of ACZONE® Gel, 5%. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ACZONE® Gel, 5%?

- Store ACZONE® Gel, 5% at room temperature 68ºF to 77ºF (20ºC to 25ºC).
- Protect ACZONE® Gel, 5% from freezing.

Keep ACZONE® Gel, 5% and all medicines out of the reach of children.

General information about the safe and effective use of ACZONE® Gel, 5%?

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ACZONE® Gel, 5% for a condition for which it was not prescribed. Do not give ACZONE® Gel, 5% to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about ACZONE® Gel, 5% that is written for health professionals.

What are the ingredients in ACZONE® Gel, 5%?

Active ingredient: dapsone
Inactive ingredients: carbomer homopolymer type C, diethylene glycol monoethyl ether, methylparaben, sodium hydroxide, and purified water, USP.

Made in the U.S.A.

ALLERGAN

For more information, call 1-800-433-8871
This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: July 2015