

# DAPSONE- dapsonе gel

## Torrent Pharmaceuticals Limited

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### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use DAPSONE GEL safely and effectively. See full prescribing information for DAPSONE GEL.

### DAPSONE gel, for topical use

Initial U.S. Approval: 1955

#### INDICATIONS AND USAGE

Dapsone gel, 7.5% is a sulfone indicated for the topical treatment of acne vulgaris in patients 12 years of age and older (1). (1)

#### DOSAGE AND ADMINISTRATION

- Apply once daily (2).
- Apply approximately a pea-sized amount of dapsone gel, 7.5% in a thin layer to the entire face. A thin layer can also be applied to other affected areas (2).
- If there is no improvement after 12 weeks, treatment with dapsone gel, 7.5% should be reassessed (2).
- For topical use only. Not for oral, ophthalmic, or intravaginal use (2).

#### DOSAGE FORMS AND STRENGTHS

Gel, 7.5% (3). (3)

#### CONTRAINDICATIONS

None (4). (4)

#### WARNINGS AND PRECAUTIONS

- Methemoglobinemia: Cases of methemoglobinemia have been reported. Discontinue dapsone gel if signs of methemoglobinemia occur (5.1).
- Hemolysis: Some patients with Glucose-6-phosphate Dehydrogenase (G6PD) deficiency using topical dapsone developed laboratory changes suggestive of hemolysis. (5.1)(8.6)

#### ADVERSE REACTIONS

Most common (incidence  $\geq 0.9\%$ ) adverse reactions are application site dryness and pruritus (6.1). (6)

**To report SUSPECTED ADVERSE REACTIONS, contact Torrent Pharma Inc. at 1-800-912-9561 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch) . (6)**

#### DRUG INTERACTIONS

- Trimethoprim/sulfamethoxazole (TMP/SMX) increases the systemic level of dapsone and its metabolites (7.1).
- Topical benzoyl peroxide used at the same time as dapsone gel, 7.5% may result in temporary local yellow or orange skin discoloration (7.2).

*Pediatric use information is approved for Almirall LLC's Aczone® (dapsone) Gel. However, due to Almirall LLC's marketing exclusivity rights, this drug product is not labeled with that information. (7)*

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

**Revised: 3/2023**

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## **FULL PRESCRIBING INFORMATION**

### **1 INDICATIONS AND USAGE**

Dapsone gel, 7.5% is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Pediatric use information is approved for Almirall LLC's Aczone® (dapsone) Gel. However, due to Almirall LLC's marketing exclusivity rights, this drug product is not labeled with that information.

### **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 dapsonе gel, 7.5%, in a thin layer to the entire face once daily. In addition, a thin layer may be applied to other affected areas once daily. Rub in dapsonе gel, 7.5%, gently and completely.

If there is no improvement after 12 weeks, treatment with dapsonе gel, 7.5%, should be reassessed.

### **3 DOSAGE FORMS AND STRENGTHS**

Gel, 7.5%. Each gram of dapsonе gel, 7.5% contains 75 mg of dapsonе in an off-white to yellow color homogeneous gel with suspended particles, no phase separation and sedimentation, free of lumps and foreign matter.

### **4 CONTRAINDICATIONS**

None.

### **5 WARNINGS AND PRECAUTIONS**

#### **5.1 Hematological Effects**

##### Methemoglobinemia

Cases of methemoglobinemia, with resultant hospitalization, have been reported postmarketing in association with twice daily dapsonе 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 dapsonе gel, 7.5% 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 dapsonе gel, 7.5% and seek immediate medical attention in the event of cyanosis.

Dapsonе can cause elevated methemoglobin levels particularly in conjunction with methemoglobin-inducing agents [see *Drug Interactions (7.4)*].

##### Hemolysis

Oral dapsonе 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.

In clinical trials, there was no evidence of clinically relevant hemolysis or hemolytic anemia in subjects treated with topical dapsonе. Some subjects with G6PD deficiency using dapsonе gel, 5% twice daily developed laboratory changes suggestive of hemolysis [see *Use in Specific Populations (8.6)*].

Discontinue dapsonе gel, 7.5%, if signs and symptoms suggestive of hemolytic anemia occur. Avoid use of dapsonе gel, 7.5% in patients who are taking oral dapsonе or antimalarial medications because of the potential for hemolytic reactions. Combination of dapsonе gel, 7.5%, with trimethoprim/sulfamethoxazole (TMP/SMX) may increase the likelihood of hemolysis in patients with G6PD deficiency [see *Drug Interactions (7.1)*].

## 5.2 Peripheral Neuropathy

Peripheral neuropathy (motor loss and muscle weakness) has been reported with oral dapsonе treatment. No events of peripheral neuropathy were observed in clinical trials with topical dapsonе treatment.

## 5.3 Skin Reactions

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

A total of 2,161 subjects were treated with dapsonе gel, 7.5%, for 12 weeks in 2 controlled clinical trials. The population ranged in age from 12 to 63 years, was 56% female, and 58% Caucasian. Adverse drug reactions that were reported in at least 0.9% of subjects treated with dapsonе gel, 7.5% appear in Table 1 below.

**Table 1. Adverse Reactions Occurring in at Least 0.9% of Subjects with Acne Vulgaris in 12-week Controlled Clinical Trials**

	<b>Dapsonе Gel, 7.5% (N=2,161)</b>	<b>Vehicle (N=2,175)</b>
Application Site Dryness	24 (1.1%)	21 (1.0%)
Application Site Pruritus	20 (0.9%)	11 (0.5%)

## 6.2 Experience with Oral Use of Dapsonе

Although not observed in the clinical trials with topical dapsonе, serious adverse reactions have been reported with oral use of dapsonе, 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

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.

The following adverse reactions have been identified during post-approval use of topical dapsons: methemoglobinemia, rash (including erythematous rash, application site rash) and swelling of face (including lip swelling, eye swelling).

## **7 DRUG INTERACTIONS**

No formal drug-drug interaction studies were conducted with dapsons gel, 7.5%.

### **7.1 Trimethoprim-Sulfamethoxazole**

A drug-drug interaction study evaluated the effect of the use of dapsons 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 dapsons and its metabolites increased in the presence of TMP/SMX. The systemic exposure from dapsons gel, 7.5% is expected to be 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 dapsons gel followed by benzoyl peroxide in patients with acne vulgaris may result in a temporary local yellow or orange discoloration of the skin and facial hair.

### **7.3 Drug Interactions with Oral Dapsons**

Certain concomitant medications (such as rifampin, anticonvulsants, St. John's wort) may increase the formation of dapsons hydroxylamine, a metabolite of dapsons associated with hemolysis. With oral dapsons 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 dapsons gel, 7.5% with drugs that induce methemoglobinemia such as sulfonamides, acetaminophen, acetanilide, aniline dyes, benzocaine, chloroquine, dapsons, 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**

#### Risk Summary

There are no available data on dapsons gel, 7.5%, use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. The systemic absorption of

dapsone in humans following topical application is low relative to oral dapsone administration [see *Clinical Pharmacology (12.3)*]. In animal reproduction studies, oral doses of dapsone administered to pregnant rats and rabbits during organogenesis that resulted in systemic exposures more than 400 times the systemic exposure at the maximum recommended human dose (MRHD) of dapsone gel, 7.5%, resulted in embryocidal effects. When orally administered to rats from the onset of organogenesis through the end of lactation at systemic exposures approximately 500 times the exposure at the MRHD, dapsone resulted in increased stillbirths and decreased pup weight [see *Data*].

The estimated background risks of major birth defects and miscarriage for the indicated population are unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

## Data

### *Animal Data*

Dapsone has been shown to have an embryocidal effect in rats and rabbits when administered orally daily to females during organogenesis at dosages of 75 mg/kg/day and 150 mg/kg/day, respectively. These dosages resulted in systemic exposures that represented approximately 1,407 times [rats] and 425 times [rabbits] the systemic exposure observed in human females as a result of use of the MRHD of dapsone gel, 7.5%, based on AUC comparisons. 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 563 times the systemic exposure that is associated with the MRHD of dapsone gel, 7.5%, based on AUC comparisons). No effects were observed on the viability, physical development, behavior, learning ability, or reproductive function of surviving pups.

## **8.2 Lactation**

### Risk Summary

There is no information regarding the presence of topical dapsone in breastmilk, the effects on the breastfed infant or the effects on milk production. Orally administered dapsone appears in human milk and could result in hemolytic anemia and hyperbilirubinemia especially in infants with G6PD deficiency. Systemic absorption of dapsone following topical application is low relative to oral dapsone administration.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for dapsone gel, 7.5% and any potential adverse effects on the breastfed child from dapsone gel, 7.5% or from the underlying maternal condition.

## **8.4 Pediatric Use**

The safety and effectiveness of dapsone gel, 7.5% for the topical treatment of acne

vulgaris have been established in patients 12 years of age and older. Use of dapsonone gel, 7.5% in patients for this indication is supported by evidence from adequate and well-controlled clinical trials in 1,066 subjects 12 years of age and older [see *Adverse Reactions (6.1)*, and *Clinical Pharmacology (12.3)*].

The safety profile for dapsonone gel, 7.5% in clinical trials was similar to the vehicle control group.

Safety and effectiveness of dapsonone gel, 7.5%, have not been established in pediatric patients below the age of 9 years.

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## 8.5 Geriatric Use

Clinical trials of dapsonone gel, 7.5%, did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

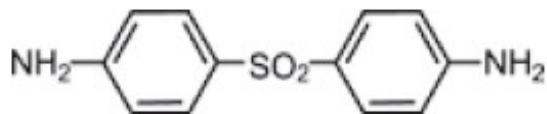
## 8.6 Glucose-6-phosphate Dehydrogenase (G6PD) Deficiency

Individuals with glucose-6-phosphate dehydrogenase (G6PD) deficiency may be more prone to methemoglobinemia and hemolysis [see *Warnings and Precautions (5.1)*].

Dapsonone gel, 5 % and vehicle were evaluated in a randomized, double-blind, cross-over design clinical study of 64 subjects 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 dapsonone gel, 5% treatment periods. Some of these subjects developed laboratory changes suggestive of hemolysis, but there was no evidence of clinically significant hemolytic anemia in this study [see *Warnings and Precautions (5.1)*].

## 11 DESCRIPTION

Dapsonone Gel, 7.5%, contains dapsonone, a sulfone, in an aqueous gel base for topical dermatologic use. Dapsonone Gel, 7.5% is an off-white to yellow color homogeneous gel with suspended particles, no phase separation and sedimentation, free of lumps and foreign matter. Chemically, dapsonone has an empirical formula of  $C_{12}H_{12}N_2O_2S$ . It is a White to creamy white crystalline powder that has a molecular weight of 248.30. Dapsonone's chemical name is 4-[(4'-aminobenzene) sulfonyl] aniline and its structural formula is:



Each gram of dapsonone gel, 7.5% contains 75 mg of dapsonone, USP in a gel of diethylene glycol monoethyl ether, methylparaben, carbomer homopolymer type C, sodium hydroxide and purified water.

## 12 CLINICAL PHARMACOLOGY

### 12.1 Mechanism of Action

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

### 12.3 Pharmacokinetics

In a pharmacokinetic study, male and female subjects 16 years of age or older with acne vulgaris (N=19) applied 2 grams of dapsonе gel, 7.5% to the face, upper chest, upper back and shoulders once daily for 28 days. Steady state for dapsonе was reached within 7 days of dosing. On Day 28, the mean dapsonе maximum plasma concentration ( $C_{max}$ ) and area under the concentration-time curve from 0 to 24 hours post dose ( $AUC_{0-24h}$ ) were  $13.0 \pm 6.8$  ng/mL and  $282 \pm 146$  ng•h/mL, respectively. The systemic exposure from dapsonе gel, 7.5% is expected to be about 1% of that from a 100 mg oral dose.

Long-term safety studies were not conducted with dapsonе gel, 7.5%, however, in a long-term clinical study of dapsonе gel, 5% treatment (twice daily), periodic blood samples were collected up to 12 months to determine systemic exposure of dapsonе and its metabolites in approximately 500 subjects. Based on the measurable dapsonе concentrations from 408 subjects (M=192, F=216), obtained at Month 3, neither gender nor race appeared to affect the pharmacokinetics of dapsonе. Similarly, dapsonе exposures were approximately the same between the age groups of 12 to 15 years (N=155) and those greater than or equal to 16 years (N=253). There was no evidence of increasing systemic exposure to dapsonе over the study year in these subjects.

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### 12.4 Microbiology

In Vivo Activity: No microbiology or immunology studies were conducted during dapsonе gel, 7.5% clinical studies.

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

## 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Dapsonе 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 340 times the systemic exposure observed in humans as a result of use of the MRHD of dapsonе gel, 7.5%, based on AUC comparisons).

No evidence of potential to induce carcinogenicity was observed in a dermal study in



which dapson 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.

Dapsone was negative in a bacterial reverse mutation assay (Ames test), and was negative in a micronucleus assay conducted in mice. Dapsone was positive (clastogenic) in a chromosome aberration assay conducted with Chinese hamster ovary (CHO) cells.

The effects of dapson gel on fertility and general reproductive performance were assessed in male and female rats following oral dosing. Dapsone reduced sperm motility at dosages of 3 mg/kg/day or greater (approximately 22 times the systemic exposure that is associated with the MRHD of dapson gel, 7.5%, based on AUC comparisons) when administered daily beginning 63 days prior to mating and continuing through the mating period. 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 187 times the systemic exposure that is associated with the MRHD of dapson gel, 7.5%, based on AUC comparisons), presumably due to reduced numbers or effectiveness of sperm, indicating impairment of fertility. When administered to female rats at a dosage of 75 mg/kg/day (approximately 1,407 times the systemic exposure that is associated with the MRHD of dapson gel, 7.5%, based on AUC comparisons) for 15 days prior to mating and for 17 days thereafter, dapson gel reduced the mean number of implantations, increased the mean early resorption rate, and reduced the mean litter size. These effects probably were secondary to maternal toxicity.

## 14 CLINICAL STUDIES

The safety and efficacy of once daily use of dapson gel, 7.5% was assessed in two 12 week multicenter, randomized, double-blind, vehicle-controlled trials. Efficacy was assessed in a total of 4,340 subjects 12 years of age and older. The majority of the subjects had moderate acne vulgaris, 20 to 50 inflammatory and 30 to 100 non-inflammatory lesions at baseline, and were randomized to receive either dapson gel, 7.5% or vehicle.

Treatment response was defined at Week 12 as the proportion of subjects who were rated "none" or "minimal" with at least a two-grade improvement from baseline on the Global Acne Assessment Score (GAAS), and mean absolute change from baseline in both inflammatory and non-inflammatory lesion counts. A GAAS score of "none" corresponded to no evidence of facial acne vulgaris. A GAAS score of "minimal" corresponded to a few non-inflammatory lesions (comedones) being present and to a few inflammatory lesions (papules/pustules) that may be present.

The GAAS success rate, mean reduction, and percent reduction in acne lesion counts from baseline after 12 weeks of treatment are presented in the following table.

**Table 2. Clinical Efficacy of Dapsone Gel at Week 12 in Subjects with Acne Vulgaris**

	Trial 1		Trial 2	
	Dapsone Gel, 7.5%	Vehicle (N=1,058)	Dapsone Gel, 7.5%	Vehicle (N=1,120)

	(N=1,044)		(N=1,118)	
<b>Global Acne Assessment Score</b>				
GAAS Success (Score 0 or 1)	30%	21%	30%	21%
<b>Inflammatory Lesions</b>				
Mean absolute reduction	16.1	14.3	15.6	14.0
Mean percent reduction	56%	49%	54%	48%
<b>Non-inflammatory Lesions</b>				
Mean absolute reduction	20.7	18.0	20.8	18.7
Mean percent reduction	45%	39%	46%	41%

## 16 HOW SUPPLIED/STORAGE AND HANDLING

Dapsone Gel is an off-white to yellow color homogeneous gel with suspended particles; no phase separation and sedimentation; free of lumps and foreign matter. It is supplied in an airless polypropylene pump containing a polypropylene bottle with a high density polyethylene piston.

Dapsone Gel, 7.5% is supplied in the following sizes:

NDC 13668-605-05                      60 gram pump

NDC 13668-605-08                      90 gram pump

**Storage:** Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F). [see USP Controlled Room Temperature]. Protect from freezing.

## 17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

### Hematological Effects

- Inform patients that methemoglobinemia can occur with topical dapsone treatment. Advise patients to seek immediate medical attention if they develop cyanosis [see *Warnings and Precautions (5.1)*].
- Inform patients who have G6PD deficiency that hemolytic anemia may occur with topical dapsone treatment. Advise patients to seek medical attention if they develop signs and symptoms suggestive of hemolytic anemia [see *Warnings and Precautions (5.1)*].

### Important Administration Instructions

- Advise patients to apply Dapsone Gel, 7.5%, once daily to the entire face [see *Dosage and Administration (2)*].
- Dapsone Gel, 7.5% is for topical use only.
- Do not apply Dapsone gel, 7.5% to eyes, mouth, or mucous membranes.

**Manufactured by:**

Encube Ethicals Pvt. Ltd.

Madkaim, Ponda, Goa – 403404 India

**Manufactured for:**



TORRENT PHARMA INC. Basking Ridge, NJ 07920

8072100  
April 2021

Revised:

<b>Patient Information</b> Dapsone (dap' sone) Gel, 7.5%
<b>Important:</b> For use on skin only (topical use). Do not use dapsone gel, 7.5% in your mouth, eyes, or vagina.
<b>What is dapsone gel, 7.5%?</b> Dapsone gel, 7.5%, is a prescription medicine used on the skin (topical) to treat acne in people 12 years and older. Dapsone gel, 7.5%, has not been studied in children under 9 years of age.
<b>Before you use dapsone gel, 7.5%, tell your doctor about all of your medical conditions, including if you:</b> <ul style="list-style-type: none"><li>● have a glucose-6-phosphate dehydrogenase deficiency (G6PD)</li><li>● have higher than normal levels of methemoglobin in your blood (methemoglobinemia)</li><li>● are pregnant or plan to become pregnant. It is not known if dapsone gel, 7.5% will harm your unborn baby.</li><li>● are breastfeeding or plan to breastfeed. Dapsone gel, 7.5% can pass into your breast milk and may harm your baby. You and your doctor should decide if you will use dapsone gel, 7.5%, or breastfeed. You should not do both.</li></ul>
<b>Tell your doctor about all the medicines you take,</b> 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 dapsone gel, 7.5% at the same time may cause your skin or facial hair to temporarily turn yellow or orange at the site of application.
<b>How do I use dapsone gel, 7.5%?</b> <ul style="list-style-type: none"><li>● Use dapsone gel, 7.5% exactly as your doctor tells you to use it.</li><li>● Apply dapsone gel, 7.5% one time a day.</li><li>● Gently wash and pat dry the areas of your skin where you will apply dapsone gel, 7.5%.</li><li>● Apply a pea-sized amount of dapsone gel, 7.5% in a thin layer to the entire face. A thin</li></ul>

layer may also be applied to other affected areas as instructed by your doctor.

- Rub dapson gel, 7.5% in gently and completely.
- Wash your hands after applying dapson gel, 7.5%.
- If your acne does not get better after using dapson gel, 7.5% for 12 weeks, talk to your doctor about continuing treatment.

### **What are the possible side effects of dapson gel, 7.5%?**

**Dapson gel, 7.5% 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 dapson gel, 7.5% 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 dapson gel, 7.5% may develop mild hemolytic anemia. Stop using dapson gel, 7.5% 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 dapson gel, 7.5% include dryness and itching of the skin being treated. These are not all of the possible side effects of dapson gel, 7.5%. 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 dapson gel, 7.5%?**

- Store dapson gel, 7.5% at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30 °C (59 °F to 86 °F). [see USP Controlled Room Temperature].
  - Protect dapson gel, 7.5% from freezing.

### **Keep dapson gel, 7.5% and all medicines out of the reach of children.**

### **General information about the safe and effective use of dapson gel, 7.5%.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use dapson gel, 7.5% for a condition for which it was not prescribed. Do not give dapson gel, 7.5% to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for information about dapson gel, 7.5% that is written for health professionals. For more information call Torrent Pharma Inc. at 1-800-912-9561.

### **What are the ingredients in dapson gel, 7.5%?**

**Active ingredient:** Dapson, USP

**Inactive ingredients:** diethylene glycol monoethyl ether, methylparaben, carbomer homopolymer type C, sodium hydroxide and purified water.

*Pediatric use information is approved for Almirall LLC's Aczone® (dapson) Gel. However, due to Almirall LLC's marketing exclusivity rights, this drug product is not labeled with that information.*

### **Manufactured by:**

Encube Ethicals Pvt. Ltd.  
Madkaim, Ponda, Goa - 403404 India

### **Manufactured for:**



TORRENT PHARMA INC. Basking Ridge, NJ 07920  
8072100

Revised: April 2021

This Patient Information has been approved by the U.S. Food and Drug Administration.

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Dapsone gel, 7.5 % 60 g Pump Label

**FOR TOPICAL USE ONLY:** Not for oral, ophthalmic or intravaginal use.

**Dosage:** Apply once daily. See package insert for dosage information.

**WARNING:** Keep out of reach of children.

Each gram of gel contains 75mg of dapsone, diethylene glycol monoethyl ether, carbomer homopolymer type C, methylparaben, sodium hydroxide and purified water.

**Storage:** Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

**Protect from freezing.**


Mfg. Lic. No.: 361  
8078459 TDG2A/00


NDC 13668-605-05


**DAPSONE  
Gel, 7.5%**

**FOR TOPICAL USE ONLY**


**Rx only      60 g**

  
N 3 13668-605-05 1



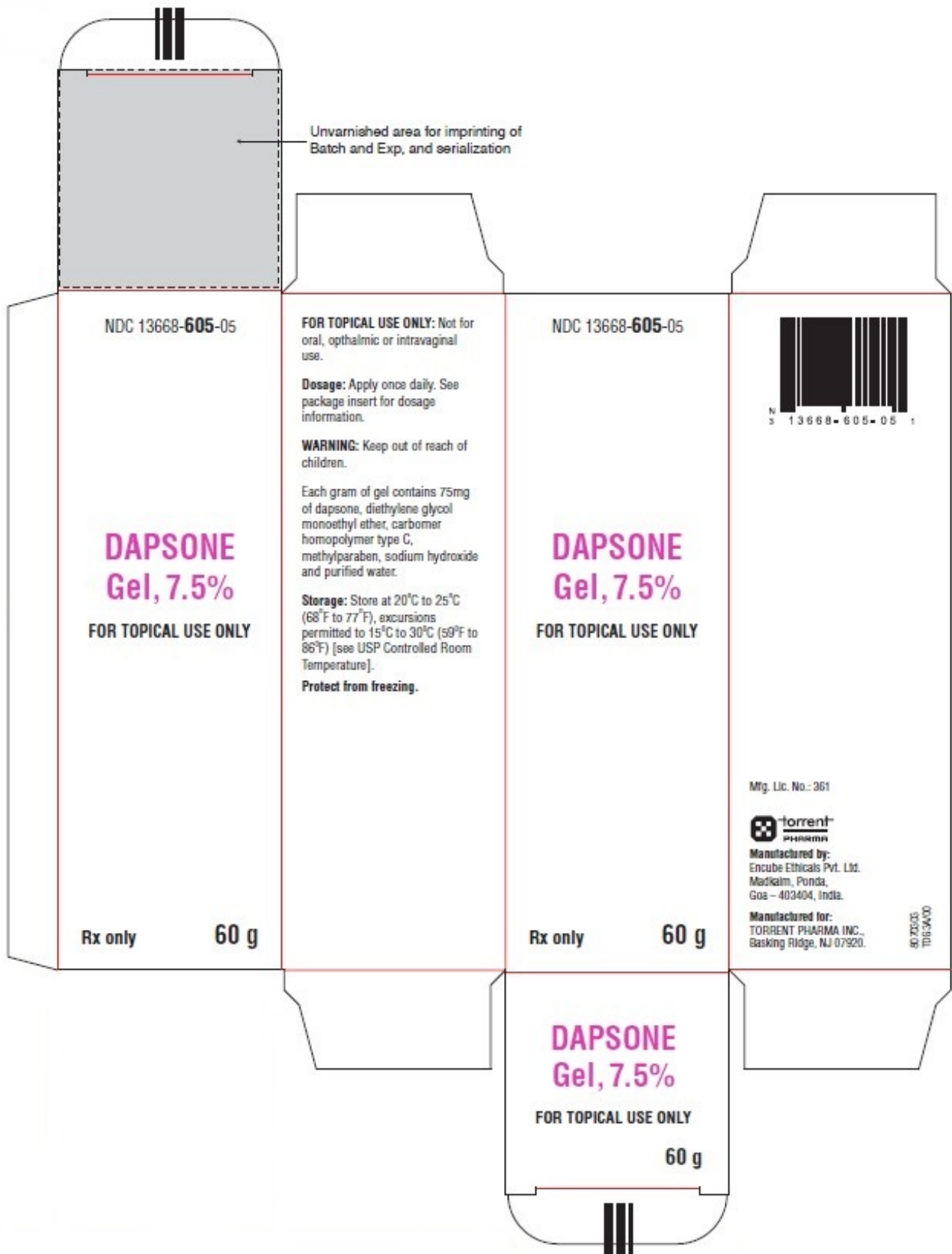
  
**Manufactured by:**  
Encube Ethicals Pvt. Ltd.  
Madkaim, Ponda,  
Goa – 403404, India.

**Manufactured for:**  
TORRENT PHARMA INC.,  
Basking Ridge, NJ 07920.



Unvarnished area for imprinting of Batch and Exp, and serialization 35 x 30 mm

Dapsone gel, 7.5 % 60 g Carton Label



Dapsone gel, 7.5 % 90 g Pump Label

**FOR TOPICAL USE ONLY:** Not for oral, ophthalmic or intravaginal use.

NDC 13668-605-08



**Dosage:** Apply once daily. See package insert for dosage information.

**WARNING:** Keep out of reach of children.

# DAPSONE Gel, 7.5%

**FOR TOPICAL USE ONLY**

Each gram of gel contains 75mg of dapsone, diethylene glycol monoethyl ether, carbomer homopolymer type C, methylparaben, sodium hydroxide and purified water.

**Storage:** Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

**Protect from freezing.**



Unvarnished area for imprinting of Batch and Exp, and serialization 35 x 30 mm

Mfg. Lic. No.: 361

8078460 TDG2B/00

**Rx only**

**90 g**

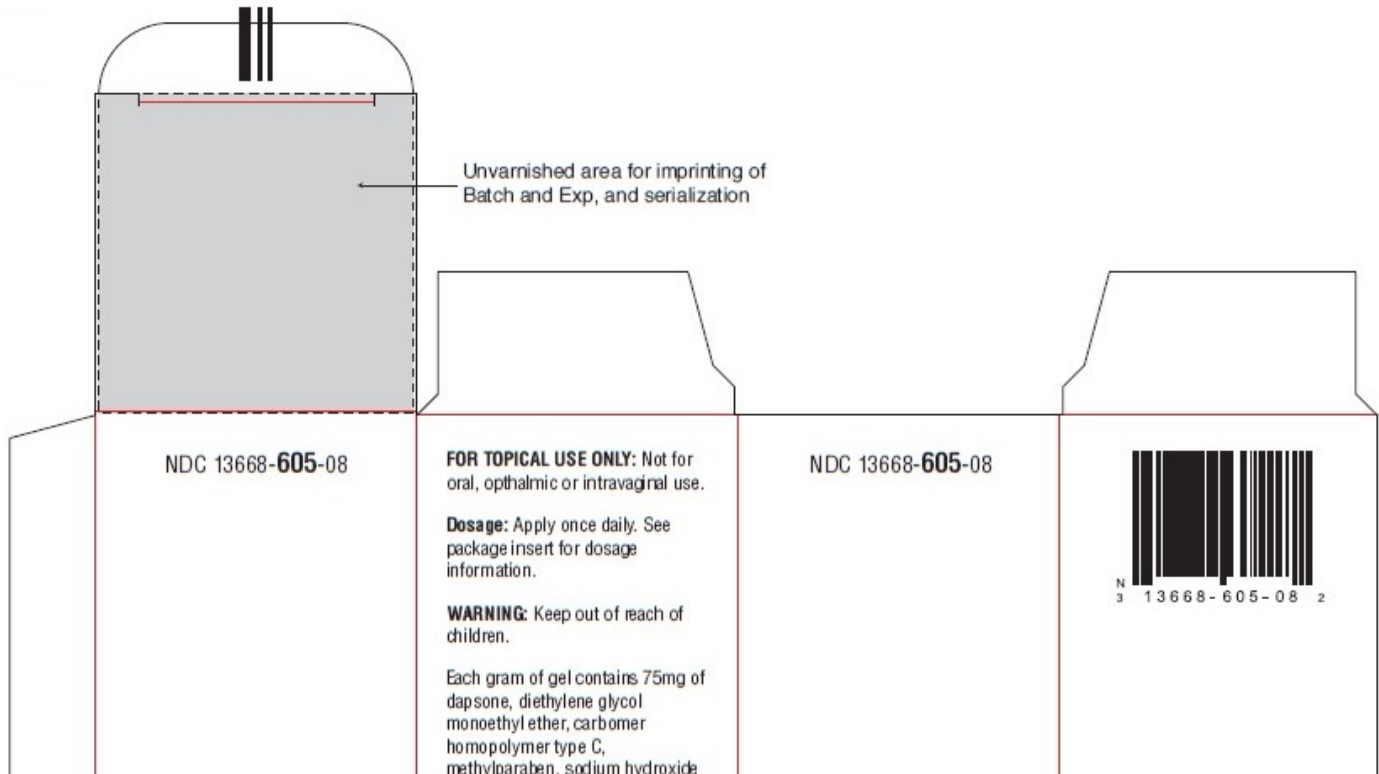


**Manufactured by:**  
Encube Ethicals Pvt. Ltd.  
Madkaim, Ponda,  
Goa - 403404, India.

**Manufactured for:**  
TORRENT PHARMA INC.,  
Basking Ridge, NJ 07920.



Dapsone gel, 7.5 % 90 g Carton Label



**DAPSONE  
Gel, 7.5%**

FOR TOPICAL USE ONLY

and purified water.

**Storage:** Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

**Protect from freezing.**

**DAPSONE  
Gel, 7.5%**

FOR TOPICAL USE ONLY

Mfg. Lic. No.: 361



**Manufactured by:**  
Encube Ethicals Pvt. Ltd.  
Madkaim, Ponda,  
Goa - 403404, India.

**Manufactured for:**  
TORRENT PHARMA INC.,  
Basking Ridge, NJ 07920.

8070304  
TDG38/00

Rx only

90 g

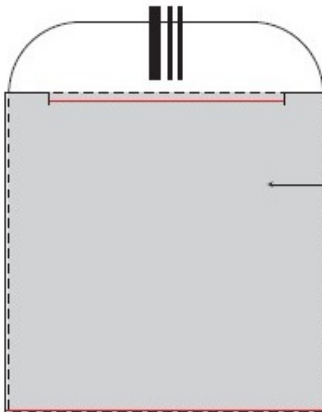
Rx only

90 g

**DAPSONE  
Gel, 7.5%**

FOR TOPICAL USE ONLY

90 g



Unvarnished area for imprinting of  
Batch and Exp, and serialization

NDC 13668-605-08

**FOR TOPICAL USE ONLY:** Not for  
oral, ophthalmic or intravaginal use.

**Dosage:** Apply once daily. See  
package insert for dosage  
information.

NDC 13668-605-08





**DAPSONE  
Gel, 7.5%**

FOR TOPICAL USE ONLY

**WARNING:** Keep out of reach of children.

Each gram of gel contains 75mg of dapsone, diethylene glycol monoethyl ether, carbomer homopolymer type C, methylparaben, sodium hydroxide and purified water.

**Storage:** Store at 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

**Protect from freezing.**

**DAPSONE  
Gel, 7.5%**

FOR TOPICAL USE ONLY

Rx only 90 g

Rx only 90 g

Mfg. Lic. No.: 361



**Manufactured by:**  
Encube Ethicals Pvt. Ltd.  
Madkaim, Ponda,  
Goa - 403404, India.

**Manufactured for:**  
TORRENT PHARMA INC.,  
Basking Ridge, NJ 07920.

8070304  
T063800

**DAPSONE  
Gel, 7.5%**

FOR TOPICAL USE ONLY

90 g



**DAPSONE**

dapsone gel

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:13668-605
<b>Route of Administration</b>	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DAPSONE (UNII: 8W5C518302) (DAPSONE - UNII:8W5C518302)	DAPSONE	75 mg in 1 g		
Inactive Ingredients				
Ingredient Name	Strength			
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A18X02B)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0K00R)				
Product Characteristics				
Color	yellow (off-white to yellow color)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13668-605-05	1 in 1 CARTON	02/10/2022	
1		60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:13668-605-08	1 in 1 CARTON	02/10/2022	
2		90 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA214722	02/10/2022		

**Labeler** - Torrent Pharmaceuticals Limited (916488547)

**Registrant** - Torrent Pharma, Inc. (790033935)

### Establishment

Name	Address	ID/FEI	Business Operations
Encube Ethicals Pvt. Ltd.		725076298	analysis(13668-605) , label(13668-605) , manufacture(13668-605) , pack(13668-605)

