

## Safety Data Sheet

### Adapalene and benzoyl peroxide topical gel

Strength: 0.3%/2.5%

Pack Size: 45 gram

Pack Size: 60 gram

NDC 72578-119-04

NDC 72578-119-02

Revision No.: 01

### Emergency Overview

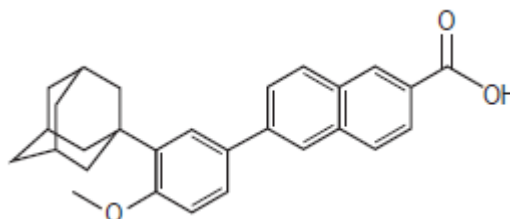
Adapalene and benzoyl peroxide topical gel is a combination of adapalene, a retinoid and benzoyl peroxide and is indicated for the topical treatment of acne vulgaris

### Section 1: Identification

**Product Name:** Adapalene and benzoyl peroxide topical gel

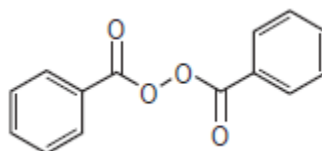
**Formula:** Adapalene:  $C_{28}H_{28}O_3$  / Benzoyl peroxide:  $C_{14}H_{10}O_4$

**Chemical Name:** Adapalene: (6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid)



**Molecular Weight:** 412.5

**Chemical Name:** Benzoyl peroxide is dibenzoyl peroxide



**Molecular Weight:** 242.23

**Description:** Adapalene and benzoyl peroxide topical gel, 0.3%/2.5% is a white to very pale-yellow opaque gel for topical use containing adapalene, USP 0.3% and benzoyl peroxide 2.5%.

**Dosage forms and strengths:** Each gram of adapalene and benzoyl peroxide topical gel contains 3 mg (0.3%) adapalene, USP and 25 mg (2.5%) benzoyl peroxide, USP in a white to very pale-yellow opaque gel. Adapalene and benzoyl peroxide topical gel is available in pumps containing 45 gm or 60 gm.

### Manufacturer / supplier identification

**Distributed By** Viona Pharmaceuticals Inc.  
Cranford, NJ 07016

**Manufactured By** Cadila Healthcare Ltd. Ahmedabad, India

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<b>Address</b>	Cadila Healthcare, Ltd. Changodar (Topical Formulation facility) Plot No. 254, Opp. Laxmi Narayan Petrol Pump, N. H 8A, Ahmedabad -382210 India
<b>Contact for information</b>	Tel.: +91 2717-616430 Fax: +91 2717-616430
<b>Emergency Telephone No</b>	Tel.: +91 2717-616401
<b>Recommended use / Therapeutic Category</b>	Adapalene and benzoyl peroxide topical gel is a combination of adapalene, a retinoid and benzoyl peroxide and is indicated for the topical treatment of acne vulgaris
<b>Contradictions</b>	None

## Section 2 : Hazard (s) Identification

### Dose and Administration

#### Dosage

For topical use only. Adapalene and benzoyl peroxide topical gel is not for oral, ophthalmic or intravaginal use.

Apply a thin layer of adapalene and benzoyl peroxide topical gel to affected areas of the face and/or trunk once daily after washing. Use a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek). Avoid the eyes, lips and mucous membranes.

## Section 3: Composition / information on ingredients

**Each gram contains:** Active: Adapalene (0.3%) and benzoyl peroxide (2.5%),

**Use in Specific Population:**

### Pregnancy Category C:

There are no well-controlled trials in pregnant women treated with adapalene and benzoyl peroxide topical gel. Animal reproduction studies have not been conducted with the combination gel. Furthermore, such studies are not always predictive of human response; therefore, adapalene and benzoyl peroxide topical gel should be used during pregnancy only if the potential benefit justifies the risk to the fetus.

No teratogenic effects were observed in rats treated with oral doses of 0.15 mg to 5 mg adapalene/kg/day, up to 8 times (mg/m<sup>2</sup> /day) the maximum recommended human dose (MRHD) of 2 grams of adapalene and benzoyl peroxide topical gel. However, teratogenic changes were observed in rats and rabbits when treated with oral doses of  $\geq 25$  mg adapalene/kg/day representing 41 times and 81 times MRHD, respectively. Findings included cleft palate, microphthalmia, encephalocele and skeletal abnormalities in rats; and umbilical hernia, exophthalmos and kidney and skeletal abnormalities in rabbits.

Dermal teratology studies conducted in rats and rabbits at doses of 0.6 mg to 6 mg adapalene/kg/day (9.7 times to 19.5 times MRHD) exhibited no fetotoxicity and only minimal increases in supernumerary ribs in both species and delayed ossification in rabbits.

**Nursing Mothers:**

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It is not known whether adapalene or benzoyl peroxide is excreted in human milk following use of adapalene and benzoyl peroxide topical gel. Because many drugs are excreted in human milk, caution should be exercised when adapalene and benzoyl peroxide topical gel is administered to a nursing woman.

#### Pediatric Use:

Safety and effectiveness of adapalene and benzoyl peroxide topical gel in pediatric patients under the age of 12 have not been established.

#### Geriatric Use:

Clinical studies of adapalene and benzoyl peroxide topical gel did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects.

#### Section 4: First -aid measures

**INGESTION:** Accidental ingestion of product may necessitate medical attention. In case of accidental ingestion dilute with fluids (water or milk) and treat symptomatically. Do not induce vomiting. Never give anything by mouth to an unconscious person. Contact the nearest Poison Control Center or local emergency number. Provide an estimate of the time and amount of the substance swallowed.

**EYES:** If the product is in the eyes, do not rub eyes. Flush with copious amount of lukewarm water for at least 15 minutes. Open and close eyelid to ensure thorough irrigation. If irritation persists contact a physician.

**SKIN:** If redness, dryness or other signs of irritation occur wash the affected area with warm water and soap. If irritation persists contact a physician. Allergic skin rash may occur

**INHALATION:** If respiratory irritation occurs, remove individual to fresh air.

**MEDCAL CONDITIONS AGGRAVATED BY EXPOSURE:** None known

#### Section 5: Fire -fighting measures

**Flashpoint:** Not determined.

**Autoignition Temperature:** Not applicable.

**Flammable Limits & Method of Determination (In Air by Volume, %):** Not applicable.

**EXPLOSION HAZARD:** This product is non-flammable

**EXTINGUISHING METHODS:** Foam, CO<sub>2</sub>, dry chemical powder, water spray, sand/earth as applicable to surrounding fire conditions.

**FIRE-FIGHTING PROCEDURES:** As in any fire, wear MSHA/NIOSH approved self-

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contained breathing apparatus (pressure-demand) and full protective gear as applicable to surrounding fire conditions.

## Section 6: Accidental Release Measures

### PROCEDURES FOR SPILL/LEAK CLEAN-UP:

Caution! Floor may become slippery. Absorb spilled material with inert material such as sawdust, sand or earth. Cleaning may require use of steam, solvents or detergents

### DISPOSAL METHOD

Sweep up and dispose of in accordance with Federal, State and local regulation.

## Section 7: Handling and Storage

### HANDLING

- Protect from light.
- Keep out of reach of children.
- Keep away from heat.

### Storage Conditions

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature].

### Special Precautions

Spilled material may present a slipping hazard if left unattended.  
Clean spills promptly.

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#### Section 8: Exposure controls/personal protection

**Eye Protection:** None required under normal conditions or use. Avoid eye contact, moderate irritation may result. May cause irritation in some sensitive individuals.

**Hand Protection:** Not required under normal conditions of use. May cause skin irritation in some sensitive individuals.

**Body Protection:** None required.

**Respiratory Protection:** None required.

#### Section 9: Physical and chemical properties

**Appearance Physical form** Adapalene and benzoyl peroxide topical gel Opaque, white to slightly yellow.

**Fragrance** Odorless

#### Section 10: Stability and reactivity

**STABILITY:** Stable at ambient temperature and under normal conditions of use as described in storage conditions.

**REACTIVITY:** Stable

**HAZARDOUS DECOMPOSITION PRODUCTS:** On combustion or on thermal decomposition (pyrolysis) releases: Carbon oxides (CO, CO<sub>2</sub>), Benzoic acid, Benzene, Phenyl benzoate, biphenyl, diphenyl, acryl aldehyde, Nitrogen oxides, Sulphur oxide.

**HAZARDOUS POLYMERIZATION:** Will not occur.

**CONDITIONS TO AVOID:** Open flames, high heat, direct sunlight and freezing

**INCOMPATIBLE SUBSTANCES:** Strong oxidizing agents. Strong acids. Strong bases. Strong reducing agents. Heavy Metals.

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### Section 11: Toxicological information

- TOXICITY DATA:** This product has not been tested on animals to obtain toxicological data.
- CHRONIC TOXICITY:** Finished product is not expected to have chronic health effects. There is no specific data for this product.
- SUSPECTED CARCINOGEN:** Finished product is not expected to be carcinogenic. There is no specific data for this product.

### Section 12: Ecological information

- ENVIRONMENTAL STABILITY:** There is no specific data for this product.
- EFFECTS ON PLANTS AND ANIMALS:** There is no specific data for this product.
- EFFECTS ON AQUATIC LIFE:** Toxic to aquatic life.

### Section 13: Disposal consideration

- WASTE DISPOSAL:** Dispose of in accordance to federal, state, and local regulations.
- SPECIAL CONSIDERATIONS:** Dispose of in accordance to federal, state, and local regulations

### Section 14: Transport information

This product is not classified as hazardous under regulations of U.S. DOT 49 CFR 172.101.

- 49 CFR (GRND): Not regulated.  
IATA (AIR): Not regulated.  
IMDG (OCN): Not regulated.  
TGDR (CANADIAN GRND): Not regulated.  
ADR/RID (EU): Not regulated.  
SCT (MEXICO): Not regulated.  
ADGR (AUSTRALIA): Not regulate

### Section 15: Regulatory information

**SARA 313/302/304/311/312 CHEMICALS:** None

**OSHA:** This product contains no chemicals which are hazardous by definition of the Hazard Communication Standard (29 CFR 1910.1200).

**TSCA:** All chemical substances in this product are listed on the TSCA inventory or are otherwise exempt from inventory status.

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**CERCLA REPORTABLE QUANTITY (RQ):** None

**OTHER FEDERAL REQUIREMENTS:** This product complies with the appropriate sections of the Food and Drug Administration, Code of Federal Regulations (CFR) Title 21.

**Section 16: Other information**

**REVISION INFORMATION:** Latest revision number and revision date is listed in the header of this document.

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

**Date of issue:** 07/06/2022

**Supersedes edition:** 00