

Exton, PA
September 10, 2019**ACZONE® (DAPSONE) GEL, 7.5% NOW APPROVED FOR THE TOPICAL TREATMENT OF ACNE VULGARIS IN PATIENTS 9 YEARS OF AGE AND OLDER**

- *Once daily Aczone® 7.5% Gel is proven to treat acne vulgaris in 12 week clinical studies.¹*
- *Expanded indication extends approved use of Aczone® 7.5% Gel to patients 9-11 years of age, building on 2016 FDA approval for patients 12 and older.*

EXTON, PA, September 10, 2019 — Almirall LLC announced today the FDA approval of the expanded indication for Aczone® 7.5% Gel to include patients aged 9-11. Aczone® 7.5% Gel is a prescription medicine used on the skin (topical) to treat inflammatory and non-inflammatory acne, previously approved in February 2016 for patients 12 and older.

“While acne may be commonly thought of as an issue for teenagers, according to treatment guidelines, acne is also prevalent in children under the age of 12,”² explains clinical study investigator and pediatric dermatologist, Adelaide Hebert, MD, of McGovern Medical School at UTHealth Houston. “Research revealed that treatment options like Aczone® 7.5% Gel can be used in these younger individuals who are living with the detrimental effects of acne.”

The expanded approval was based on data from an open-label safety study to assess safety, pharmacokinetics, and treatment effect of Aczone® Gel, 7.5% in 101 patients 9 to 11 years of age with acne vulgaris. Aczone® 7.5% Gel was determined to be safe and effective in this patient population.

“Acne is linked to the onset of puberty, which may start earlier,³ and pre-teen children are an impressionable age group prone to the emotional and psychosocial implications of the disease. Almirall is therefore pleased to be able to offer this FDA approved treatment option which is proven to be safe and effective in children 9 to 11 years old,”⁴ states Ayman Grada, MD, Director of Medical Affairs and R&D at Almirall, LLC.

Aczone® 7.5% Gel is one of thirteen branded products marketed in the US by Almirall, a global family-owned company focused on medical dermatology and skin health. Ron Menezes, President and General Manager at Almirall, LLC, underscores: “We are very pleased to announce this expanded indication for Aczone® 7.5% Gel which further demonstrates Almirall’s commitment to our patients and to continuous innovation in medical dermatology.”

To learn more about Aczone® 7.5% Gel, please visit aczone.com.
To learn more about Almirall LLC, please visit almirall.us.

About Aczone®

ACZONE® (dapson) Gel, 7.5%, is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION**WARNINGS AND PRECAUTIONS**Hematological Effects

Methemoglobinemia: Cases of methemoglobinemia with resultant hospitalization have been reported post marketing in association with twice-daily dapson 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 7.5% in 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-gray cyanosis seen in, eg, buccal mucous membranes, lips, and nail beds. Advise patients to discontinue ACZONE® Gel 7.5%

and seek immediate medical attention in the event of cyanosis. Dapsone can cause elevated methemoglobin levels, particularly in conjunction with methemoglobin-inducing agents.

Hemolysis: 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. In clinical trials, there was no evidence of clinically relevant hemolysis or hemolytic anemia in subjects treated with topical dapsone. Some subjects with G6PD deficiency using dapsone gel 5% twice daily developed laboratory changes suggestive of hemolysis. Discontinue ACZONE® Gel 7.5% if signs and symptoms suggestive of hemolytic anemia occur. Avoid use of ACZONE® Gel 7.5% in patients who are taking oral dapsone or antimalarial medications because of the potential for hemolytic reactions. Combination of ACZONE® Gel 7.5% with trimethoprim/sulfamethoxazole (TMP/SMX) may increase the likelihood of hemolysis in patients with G6PD deficiency.

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 dapsone treatment.

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 dapsone treatment. These types of skin reactions were not observed in clinical trials with topical dapsone treatment.

ADVERSE REACTIONS

The most common adverse reactions of ACZONE® Gel 7.5% are dryness and pruritus at the application site. Methemoglobinemia has been identified during postmarketing use of topical dapsone.

DRUG INTERACTIONS

Topical application of dapsone 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.

[Please click here for the full Prescribing Information.](#)

About Almirall

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying Science to provide medical solutions to patients & future generations. Our efforts are focused on fighting against skin health diseases and helping people feel and look their best. We support healthcare professionals in their quest to find continuous improvement to treatments, by bringing our innovative solutions where they are needed. The company, founded in 1943 and with headquarters in Barcelona, is listed on the Spanish Stock Exchange (ticker: ALM). Almirall has become a key element of value creation to society according to its commitment with its major shareholders and its decision to help others, to understand their challenges and to use Science to help provide them with solutions for real life health challenges. Total revenue in 2017 was 755.8 million euros and more than 1,830 employees are devoted to Science.

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References

1. ACZONE® (dapson) Gel, 7.5% Prescribing Information.
2. Eichenfield LF, et al. Evidence-Based Recommendations for the Diagnosis and Treatment of Pediatric Acne. *Pediatrics*. 2013 May;131(3):Supplement.
3. Goldberg JL, et al. Changing Age of Acne Vulgaris Visits: Another Sign of Earlier Puberty? *Pediatr Dermatol*. 2011 Nov-Dec;28(6):645-8.
4. The Johns Hopkins University (2019). *Acne in Children*. [online] Available at: <https://www.hopkinsmedicine.org/health/conditions-and-diseases/acne-in-children> [Accessed 30 Jul. 2019].