

ZORYVE® (roflumilast)

Category:

Best Biotechnology Product

Company Name:

Arcutis Biotherapeutics

Product/Solution Name:

ZORYVE® (roflumilast)

Compound/Tech Name:

Topical roflumilast

Trade Name:

ZORYVE®

Corporate Name:

ZORYVE® (roflumilast)

Date of Approval:

2022-07-29

Indications:

ZORYVE® (roflumilast) topical foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

ZORYVE® (roflumilast) cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.

ZORYVE® (roflumilast) cream, 0.15%, is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

ZORYVE® (roflumilast) topical foam, 0.3%, is indicated for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and

older.

Therapeutic Areas:

Dermatology, Immunology

General Information File Document upload:

N/A

Background information and need for drug / device:

Our skin is the largest and most visible organ of the body, and chronic immune-mediated skin diseases like seborrheic dermatitis, atopic dermatitis, and plaque psoriasis can affect a person's physical and mental well-being, negatively impact a person's quality of life, and may lead to alterations in a person's daily activities to avoid social stigma.^{1,2,3} Together, these lifelong skin conditions impact over 40 million people in the U.S.⁴⁻⁷

Because of the chronic nature of these diseases, individuals may feel hopeless and live with fearful anticipation of unexpected outbreaks of symptoms on their skin or their children's skin.^{1,2}

Despite 9 in 10 individuals with these conditions using topical therapies, innovation in topical treatments has remained limited.⁸ Traditional topical therapeutics, including steroids, come with safety and efficacy concerns related to long-term use, especially for children and adolescents.^{4,9} Depending on the body location affected, such as hair-bearing regions like the scalp or sensitive areas including the face, many traditional topical therapies must be avoided entirely or require complex rotational regimens.¹⁰

Furthermore, many current treatments require multiple daily applications, leave behind greasy residues, or cause irritation, which combined with fears about side effects, significantly impact adherence.^{11,12} In addition, all currently approved topical anti-inflammatory drugs other than those developed by Arcutis contain skin penetration enhancers, to be able to deliver therapeutic concentrations of the drug despite the barrier properties of skin. The skin penetration propylene glycol (PG) elicits an allergenic response in a significant number of patients.¹³ When PG is used synergistically with other skin penetration enhancers, such as oleyl alcohol, the otherwise transient compromise of skin barrier function is prolonged and allows environmental irritants and allergens to further inflame the patient's skin. These enhancers are especially problematic for skin conditions like seborrheic dermatitis and atopic dermatitis that have an inherent skin barrier defect.^{14,15} High concentrations of

short-chain alcohols like isopropyl alcohol and ethanol, common in topical medications, also cause significant drying of skin and hair.¹⁶

Thus, there is an urgent need for a new, well-tolerated, effective topical therapy that addresses the needs of people with immune-mediated skin diseases, especially those affecting the skin barrier.

Background File Document upload:

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History of the development of the solution/product:

Driven by the belief that people with chronic skin conditions deserve better, Arcutis developed two formulations of a next-generation, best-in-class topical phosphodiesterase-4 (PDE-4) inhibitor—a foam and a cream. PDE-4 is an established target in dermatology. Roflumilast, a PDE-4 inhibitor, was chosen due to its potency, selectivity, and high binding affinity.¹⁷ The hydrophobicity of roflumilast presented a challenge for developing a moisturizing, water-based formulation.

Arcutis needed to address several challenges when developing its topical formulations to ensure products were highly effective, well tolerated, could be applied anywhere on the skin (including hair-bearing areas), and were cosmetically acceptable to patients.

Arcutis formulated ZORYVE (roflumilast) foam and cream to overcome this challenge and ensure medication was delivered without disrupting the skin barrier of patients with chronic skin conditions. In fact, these are the first topical prescription treatments to include Crodafoes CES emulsifying wax. Crodafoes CES is a mild emulsifier and conditioning agent used in the cosmetic industry,¹⁸ but until ZORYVE, it had not been approved by the FDA for use in a prescription product.

ZORYVE is uniquely formulated as an emollient, water-based product without fragrances or penetration enhancers, which are commonly used in prescription topicals and are known to irritate the skin, causing local tolerability issues.¹⁸⁻²¹ Arcutis' formulations are also pH balanced to the skin and contain moisturizing properties.^{7,19,22} Arcutis has been successful in formulating its topicals without the use of either penetration enhancers or short-chain alcohols.

In July 2022, ZORYVE cream 0.3% was approved by the FDA as the first and only topical PDE-4 inhibitor for the treatment of plaque psoriasis and in October 2023, the indication was expanded to include children down to age 6.²³

The FDA approved ZORYVE foam 0.3% as the first topical drug with a new mechanism of action for seb derm in over two decades in December 2023.^{8,24} In clinical trials,

treatment with ZORYVE foam resulted in rapid improvement in disease clearance and reduction in symptoms including itch, one of the most bothersome symptoms of seb derm.⁸ Nearly 80% of individuals achieved the primary efficacy endpoint and just over 50% of individuals reached complete clearance at Week 8.

In May 2025, the FDA approved ZORYVE foam 0.3% as treatment for plaque psoriasis of the scalp and body in individuals 12 years of age and older.²⁵ In clinical trials, ZORYVE foam demonstrated significant improvements in signs and symptoms of psoriasis on both the body and scalp.^{26,27} ZORYVE foam, which can be used on all skin and hair types, fills a critical unmet need as it was intentionally formulated to meet the total need of individuals with psoriasis, including hard-to-treat areas of the body.²⁵

In July 2024, ZORYVE® cream 0.15% was approved by the FDA for the treatment of mild-to-moderate atopic dermatitis in individuals ages 6 and older. 9 out of 10 people saw symptom improvement with ZORYVE cream.²⁸

Lastly, the FDA has accepted a sNDA for ZORYVE cream 0.05% for the treatment of mild-to-moderate atopic dermatitis in children aged 2 to 5 years old.²⁹

Development File Document upload:

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Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

Following decades without significant innovation in topical treatment options for chronic immune-mediated skin conditions, ZORYVE offers those living with these conditions, and their healthcare providers, new hope. ZORYVE possesses several unique qualities that address the unmet needs of patients and is uniquely designed to simplify disease management for millions of people living with chronic, immune-mediated inflammatory skin diseases.

Notably, ZORYVE offers a convenient, once-daily, steroid-free, water-based topical treatment option that can be used anywhere on the body as well as across all skin and hair types and the full spectrum of disease severity. The unique topical formulations of ZORYVE allow the product to spread easily and absorb quickly.^{7,22-25} This combination of a novel formulation and the properties of roflumilast contribute to ZORYVE's ability to be used once a day, on all affected areas of the body, with no limitations on duration of use.²³⁻²⁵

Given that seb derm and psoriasis can affect individuals across all demographics, ZORYVE foam was optimally designed for use on the scalp and other hair-bearing areas.

To ensure its suitability for a wide variety of skin and hair types, Arcutis confirmed with industry experts that the formulation of ZORYVE foam does not include any ingredients that may adversely affect hair and skin health, affirming its status as a safe and effective treatment option for all hair types.²²

Additionally, the National Psoriasis Foundation recently awarded ZORYVE cream and ZORYVE foam its Seal of Recognition, which highlights and recognizes products created or intended to be non-irritating and safe for those living with psoriatic disease.

ZORYVE is the first and only topical PDE-4 inhibitor approved for the treatment of plaque psoriasis and the only topical for which efficacy has been specifically demonstrated in the treatment of intertriginous psoriasis, highlighting its novelty.²⁴ For seb derm, ZORYVE is the first topical drug with a new mechanism of action in over two decades.⁸ As a steroid-free option that can be used anywhere on the body, especially in difficult-to-treat areas, with no limitations on duration, ZORYVE is a meaningful innovation to simplify disease management for topical treatment of immune-mediated skin conditions.

Arcutis remains committed to solving today's biggest medical dermatology challenges and has initiated trials for roflumilast cream 0.05% for the treatment of mild to moderate atopic dermatitis in infants aged three to 24 months.

As a result, ZORYVE is now the #1 prescribed branded topical to treat three major inflammatory dermatoses - atopic dermatitis, seborrheic dermatitis and plaque psoriasis. In addition, clinical research is ongoing to ascertain whether this novel PDE-4 inhibitor can be used to treat other chronic skin conditions.

Innovation File Document upload:

N/A

Please provide appropriate references (PubMed, Abstract, Website):

<https://www.zoryve.com>

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