

Category

Best Biotechnology Product

General Information**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.

words remaining :

395

Therapeutic Areas *

Dermatology, Immunology

words remaining :

498

*Kindly clearly label your files with company name and asset name.

Background information and need for drug / device

(please be as specific as possible in your description; limit 500 words)

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.

words remaining :

151

*Kindly clearly label your files with company name and asset name.

Attached Files:

- [Arcutis ZORYVE Platform longer version.docx](#)

History of the development of the solution/product ***(please be as specific as possible in your description; 500 words)**

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 Crodafos CES emulsifying wax. Crodafos 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

words remaining :

4

*Kindly clearly label your files with company name and asset name.

Attached Files:

- [Arcutis ZORYVE Platform 250707 FINAL shorter version.docx](#)

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.

words remaining :

72

*Kindly clearly label your files with company name and asset name.

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

<https://www.zoryve.com>

<https://www.zoryvehcp.com/>

<https://www.arcutis.com/news-media/>

Tuckman A. The Potential Psychological Impact of Skin Conditions. *Dermatol Ther (Heidelb)*. 2017;7(Suppl 1):53-57. doi:10.1007/s13555-016-0169-7

2 Bhosle MJ, Kulkarni A, Feldman SR, Balkrishnan R. Quality of life in patients with psoriasis. *Health Qual Life Outcomes*. 2006;4:35. Published 2006 Jun 6. doi:10.1186/1477-7525-4-35

3 Szepietowski JC, Reich A, Wesołowska-Szepietowska E, Baran E; National Quality of Life in Dermatology Group. Quality of life in patients suffering from seborrheic dermatitis: influence of age, gender and education level. *Mycoses*. 2009;52(4):357-363. doi:10.1111/j.1439-0507.2008.01624.x

4 Clark, G. W., Pope, S. M., & Jaboori, K. A. (2015). Diagnosis and treatment of seborrheic dermatitis. *American family physician*, 91(3), 185-190.

5 Johnson M, Roberts J. Advance data from vital and health statistics. US Dept of Health, Education, and Welfare; 1977. Accessed June 26, 2024. <https://stacks.cdc.gov/view/cdc/61629>

6 NEA. Atopic dermatitis. National Eczema Association.

<https://nationaleczema.org/eczema/types-of-eczema/atopic-dermatitis/>

7 Data on file: REF-00955. Arcutis Biotherapeutics, 2022.

8 Data on file. Arcutis Biotherapeutics, Inc.

9 Merola JF, Qureshi A, Husni ME. Underdiagnosed and undertreated psoriasis: Nuances of treating psoriasis affecting the scalp, face, intertriginous areas, genitals, hands, feet, and nails. *Dermatol Ther*. 2018;31(3):e12589. doi:10.1111/dth.12589

10 Aldredge LM, Higham RC. Manifestations and management of difficult-to-treat psoriasis. *J Am Assoc Nurse Pract*. 2018;10(4):189-197.

11 LeBovidge JS, Elverson W, Timmons KG, et al. Multidisciplinary interventions in the management of atopic dermatitis. *J Allergy Clin Immunol*. 2016;138(2):325-334. doi:10.1016/j.jaci.2016.04.003

12 Patel NU, D'Ambra V, Feldman SR. Increasing adherence with topical agents for atopic dermatitis. *Am J Clin Dermatol*. 2017;18(3):323-332. doi:10.1007/s40257-017-0261-5

13 Fakhre F, de Vries J, Chandani B, et al. 54418 Uncovering a Hidden Threat: Propylene Glycol as an Underrecognized Allergen and Cause of Allergic Contact Dermatitis. *J Amer Academy of Dermatology*. 2024; 91(3): Suppl AB95. DOI: 10.1016/j.jaad.2024.07.382.

14 Rousel J, Nădăban A, Saghari M, et al. Lesional skin of seborrheic dermatitis patients is characterized by skin barrier dysfunction and correlating alterations in the stratum corneum ceramide composition. *Exp Dermatol*. 2024 Jan;33(1):e14952. doi: 10.1111/exd.14952.

15 Kim BE and Leung DYM. Significance of Skin Barrier Dysfunction in Atopic Dermatitis. *Allergy Asthma Immunol Res*. 2018 Jan 22;10(3):207-215. doi: 10.4168/aair.2018.10.3.207.

16 Polaskey MT, Woolery-Llloyd H, Osborne D, et al. When Patient Diversity Informs Formulation: Reimagining Treatment for Seborrheic Dermatitis. *Dermatol Ther (Heidelb)*. 2024 Apr 27;14(5):1071-

1077. doi: 10.1007/s13555-024-01161-9.

17 Dong C, Virtucio C, Zemska O, et al. Treatment of Skin Inflammation with Benzoxaborole Phosphodiesterase Inhibitors: Selectivity, Cellular Activity, and Effect on Cytokines Associated with Skin Inflammation and Skin Architecture Changes. *J Pharmacol Exp Ther*. 2016;358(3):413-422.

doi:10.1124/jpet.116.232819

18 Berk D, Osborne DW. Krafft temperature of surfactants in vehicles for roflumilast and pimecrolimus cream and effects on skin tolerability. Poster presented at: The Society for Investigative Dermatology Annual Meeting; May 18-22, 2022; Portland, OR.

19 Lessmann H, Schnuch A, Geier J, Uter W. Skin-sensitizing and irritant properties of propylene glycol. *Contact Dermatitis*. 2005;53(5):247-259. doi:10.1111/j.0105-1873.2005.00693.x

20 Del Rosso JQ, Kircik LH, Zeichner J, Stein Gold L. The Clinical Relevance and Therapeutic Benefit of Established Active Ingredients Incorporated into Advanced Foam Vehicles: Vehicle Characteristics Can Influence and Improve Patient Outcomes. *J Drugs Dermatol*. 2019;18(2s):s100-s107.

21 Draelos ZD, et al. Assessment of the Vehicle for Roflumilast Cream Compared to a Commercially Marketed, Ceramide-Containing Moisturizing Cream in Patients with Mild Eczema. Presented at RAD Virtual Conference; December 11-13, 2021.

22 Chovatiya R, Polaskey MT, Lain E, et al. Putting the Formulation Back in Foam: Optimizing Seborrheic Dermatitis Treatment Across Diverse Hair Types. *J Clin Aesthet Dermatol*. 2024;17(5):30-33.

23 ZORYVE® cream. Prescribing information. Arcutis Biotherapeutics, Inc; 2024.

24 ZORYVE® foam. Prescribing information. Arcutis Biotherapeutics, Inc; 2023.

25 ZORYVE. Prescribing Information. Arcutis Biotherapeutics, Inc; 2025.

26 Gooderham, M., Bagel, J., Forman, S., et al. 2025. Patient-Reported Outcomes with Roflumilast Foam 0.3% in Individuals with Psoriasis of the Scalp and Body in the Phase 3 ARRECTOR Trial. *SKIN The Journal of Cutaneous Medicine*. 9, 2 (Mar. 2025), s525. DOI:https://doi.org/10.25251/skin.10.suppl.525.

27 Kircik LH, Alonso-Llamazares J, et al. Once-daily roflumilast foam 0.3% for scalp and body psoriasis: a randomized, double-blind, vehicle-controlled phase IIb study. *Br J Dermatol*. 2023 Sep 15;189(4):392-399. doi: 10.1093/bjd/ljad182. PMID: 37279795.

28 Simpson EL, et al. Roflumilast Cream, 0.15%, for Atopic Dermatitis in Adults and Children: INTEGUMENT-1 and INTEGUMENT-2 Randomized Clinical Trials. *JAMA Dermatol*. 2024 Nov 1;160(11):1161-1170. doi: 10.1001/jamadermatol.2024.3121. Erratum in: *JAMA Dermatol*. 2025 Apr 23. doi: 10.1001/jamadermatol.2025.1153. PMID: 39292443; PMCID: PMC11411450.

29 Arcutis Biotherapeutics, Inc. <https://www.arcutis.com/u-s-fda-accepts-supplemental-new-drug-application-for-arcutis-zoryve-roflumilast-cream-0-05-for-the-treatment-of-children-aged-2-to-5-with-mild-to-moderate-atopic-dermatitis/>; Accessed 1 May 2025.

- <https://pubmed.ncbi.nlm.nih.gov/36125472/> - Lebwohl MG, Kircik LH, Moore AY, et al. Effect of Roflumilast Cream vs Vehicle Cream on Chronic Plaque Psoriasis: The DERMIS-1 and DERMIS-2 Randomized Clinical Trials. *JAMA*. 2022;328(11):1073-1084. doi:10.1001/jama.2022.15632
https://jamanetwork.com/journals/jama/fullarticle/2796379?guestAccessKey=8f1d4942-2349-4b55-99f4-e14eca508fe8&utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_conter
- <https://pubmed.ncbi.nlm.nih.gov/36370336/> - Stein Gold, L., Alonso-Llamazares, J., Draelos, Z.D. et al. Effect of Roflumilast Cream (ARQ-151) on Itch and Itch-Related Sleep Loss in Adults with Chronic Plaque Psoriasis: Patient-Reported Itch Outcomes of a Phase 2b Trial. *Am J Clin Dermatol* 24, 305-313 (2023). <https://doi.org/10.1007/s40257-022-00739-3>

- <https://pubmed.ncbi.nlm.nih.gov/38253129/> - Blauvelt A, Draelos ZD, Stein Gold L et al. Roflumilast foam 0.3% for adolescent and adult patients with seborrheic dermatitis: A randomized, double-blinded, vehicle-controlled, phase 3 trial. *JAAD*. 90(5), 986-993 (May 2024).
[https://www.jaad.org/article/S0190-9622\(24\)00107-5/fulltext](https://www.jaad.org/article/S0190-9622(24)00107-5/fulltext)
- <https://pubmed.ncbi.nlm.nih.gov/38253129/> - Blauvelt A, Draelos ZD, Stein Gold L, Alonso-Llamazares J, Bhatia N, DuBois J, Forman SB, Gooderham M, Green L, Guenther ST, Hebert AA, Lain E, Moore AY, Papp KA, Zirwas M, Kato S, Snyder S, Krupa D, Burnett P, Berk DR, Chu DH. Roflumilast foam 0.3% for adolescent and adult patients with seborrheic dermatitis: A randomized, double-blinded, vehicle-controlled, phase 3 trial. *J Am Acad Dermatol*. 2024 May;90(5):986-993. doi: 10.1016/j.jaad.2023.12.065. Epub 2024 Jan 20. PMID: 38253129. [https://www.jaad.org/article/S0190-9622\(24\)00107-5/fulltext](https://www.jaad.org/article/S0190-9622(24)00107-5/fulltext)
- <https://pubmed.ncbi.nlm.nih.gov/38472524/> - Chang CH, Chovatiya R. More yeast, more problems?: reevaluating the role of *Malassezia* in seborrheic dermatitis. *Arch Dermatol Res*. 2024 Mar 12;316(4):100. doi: 10.1007/s00403-024-02830-7. PMID: 38472524. <https://doi.org/10.1007/s00403-024-02830-7>
- <https://pubmed.ncbi.nlm.nih.gov/38430133/> - Chang CH, Hanna E, Polaskey MT, Nunes D, Kim J, Chovatiya R. Prevalence and association of psoriasis with seborrheic dermatitis: A systematic review and meta-analysis. *Clin Exp Dermatol*. 2024 Mar 2;llae072. doi: 10.1093/ced/llae072. Epub ahead of print. PMID: 38430133. <https://academic.oup.com/ced/advance-article-abstract/doi/10.1093/ced/llae072/7617777?redirectedFrom=fulltext>
- <https://pubmed.ncbi.nlm.nih.gov/38779376/> - Chovatiya R, Polaskey MT, Lain E, Schlesinger T, Woolery-Lloyd H, Burnett P, Hanna D. Putting the Formulation Back in Foam: Optimizing Seborrheic Dermatitis Treatment Across Diverse Hair Types. *J Clin Aesthet Dermatol*. 2024 May;17(5):30-33. PMID: 38779376; PMCID: PMC11107903. <http://www.ncbi.nlm.nih.gov/pmc/articles/pmc11107903/>
- <https://pubmed.ncbi.nlm.nih.gov/36890712/> - Draelos ZD, Adam DN, Hong HC, Lebwohl MG, Lynde CW, Nahm WK, Papp KA, Pariser DM, Stein Gold L, Stewart D, Higham RC, Berk DR, Krupa D, Burnett P. Efficacy and safety of roflumilast cream for chronic plaque psoriasis with facial/neck and intertriginous area involvement: a post hoc analysis from a randomized controlled trial. *Br J Dermatol*. 2023 May 24;188(6):810-812. doi: 10.1093/bjd/ljad060. PMID: 36890712.
<https://academic.oup.com/bjd/article/188/6/810/7073297?login=false>
- <https://pubmed.ncbi.nlm.nih.gov/37500910/> - Fakhraie S, Erickson T, Chovatiya R. Evaluation of a patient education platform for seborrheic dermatitis. *Arch Dermatol Res*. 2023 Dec;315(10):2927-2930. doi: 10.1007/s00403-023-02681-8. Epub 2023 Jul 28. PMID: 37500910.
<https://doi.org/10.1007/s00403-023-02681-8>
- <https://pubmed.ncbi.nlm.nih.gov/36745371/> - Gooderham M, Kircik L, Zirwas M, Lee M, Kempers S, Draelos Z, Ferris L, Jones T, Saint-Cyr Proulx E, Bissonnette R, Bhatia N, Koppel R, Guenther S, Eads K, Welgus H, Merritt C, Elias M, Navale L, Higham R, Droege M, Berk D. The Safety and Efficacy of Roflumilast Cream 0.15% and 0.05% in Patients With Atopic Dermatitis: Randomized, Double-Blind, Phase 2 Proof of Concept Study. *J Drugs Dermatol*. 2023 Feb 1;22(2):139-147. doi: 10.36849/JDD.7295. PMID: 36745371. <https://jddonline.com/articles/the-safety-and-efficacy-of-roflumilast-cream-015-and-005-in-patients-with-atopic-dermatitis-randomized-double-blind-phase-2-proof-of-concept-study-S1545961623P0139X/>
- <https://pubmed.ncbi.nlm.nih.gov/38874893/> - Greiling T, Young M, Seal MS, Higham RC, Armstrong A. Patient Perspectives on the Prevalence and Burden of Intertriginous Psoriasis: Results from a National Survey of Adults with Psoriasis in the United States. *Dermatol Ther (Heidelb)*. 2024 Jun 14. doi: 10.1007/s13555-024-01190-4. Epub ahead of print. PMID: 38874893. <https://doi.org/10.1007/s13555-024-01190-4>
- <https://pubmed.ncbi.nlm.nih.gov/36538948/> - Jackson JM, Alexis A, Zirwas M, Taylor S. Unmet needs for patients with seborrheic dermatitis. *J Am Acad Dermatol*. 2024 Mar;90(3):597-604. doi:

10.1016/j.jaad.2022.12.017. Epub 2022 Dec 17. PMID: 36538948. [https://www.jaad.org/article/S0190-9622\(22\)03307-2/fulltext](https://www.jaad.org/article/S0190-9622(22)03307-2/fulltext)

• <https://pubmed.ncbi.nlm.nih.gov/37279795/> - Kircik LH, Alonso-Llamazares J, Bhatia N, Bukhalo M, Devani AR, Draelos ZD, DuBois J, Gooderham MJ, Kempers SE, Lain E, Lee M, Moore A, Murrell DF, Papp KA, Pariser DM, Sinclair R, Zirwas M, Burnett P, Higham RC, Krupa D, Berk DR. Once-daily roflumilast foam 0.3% for scalp and body psoriasis: a randomized, double-blind, vehicle-controlled phase IIb study. *Br J Dermatol*. 2023 Sep 15;189(4):392-399. doi: 10.1093/bjd/ljad182. PMID: 37279795. <https://academic.oup.com/bjd/article/189/4/392/7190556>

• <https://pubmed.ncbi.nlm.nih.gov/32668113/> - Lebwohl MG, Papp KA, Stein Gold L, Gooderham MJ, Kircik LH, Draelos ZD, Kempers SE, Zirwas M, Smith K, Osborne DW, Trotman ML, Navale L, Merritt C, Berk DR, Welgus H; ARQ-151 201 Study Investigators. Trial of Roflumilast Cream for Chronic Plaque Psoriasis. *N Engl J Med*. 2020 Jul 16;383(3):229-239. doi: 10.1056/NEJMoa2000073. PMID: 32668113. <https://www.nejm.org/doi/10.1056/NEJMoa2000073>

• <https://pubmed.ncbi.nlm.nih.gov/36125472/> - Lebwohl MG, Kircik LH, Moore AY, Stein Gold L, Draelos ZD, Gooderham MJ, Papp KA, Bagel J, Bhatia N, Del Rosso JQ, Ferris LK, Green LJ, Hebert AA, Jones T, Kempers SE, Pariser DM, Yamauchi PS, Zirwas M, Albrecht L, Devani AR, Lomaga M, Feng A, Snyder S, Burnett P, Higham RC, Berk DR. Effect of Roflumilast Cream vs Vehicle Cream on Chronic Plaque Psoriasis: The DERMIS-1 and DERMIS-2 Randomized Clinical Trials. *JAMA*. 2022 Sep 20;328(11):1073-1084. doi: 10.1001/jama.2022.15632. PMID: 36125472; PMCID: PMC9490499. <https://jamanetwork.com/journals/jama/fullarticle/2796379>

• <https://pubmed.ncbi.nlm.nih.gov/32845114/> - Papp KA, Gooderham M, Droege M, Merritt C, Osborne DW, Berk DR, Thurston AW, Smith VH, Welgus H. Roflumilast Cream Improves Signs and Symptoms of Plaque Psoriasis: Results from a Phase 1/2a Randomized, Controlled Study. *J Drugs Dermatol*. 2020 Aug 1;19(8):734-740. doi: 10.36849/JDD.2020.5370. PMID: 32845114.

<https://jddonline.com/articles/roflumilast-cream-improves-signs-and-symptoms-of-plaque-psoriasis-results-from-a-phase-12a-randomize-S1545961620P0734X/>

• <https://pubmed.ncbi.nlm.nih.gov/34236691/> - Papp KA, Lebwohl MG, Kircik LH, Pariser DM, Strober B, Krueger GG, Berk DR, Navale L, Higham RC. The Proposed PASI-HD Provides More Precise Assessment of Plaque Psoriasis Severity in Anatomical Regions with a Low Area Score. *Dermatol Ther (Heidelb)*. 2021 Aug;11(4):1079-1083. doi: 10.1007/s13555-021-00572-2. Epub 2021 Jul 8. PMID: 34236691; PMCID: PMC8322185. <https://doi.org/10.1007/s13555-021-00572-2>

• <https://pubmed.ncbi.nlm.nih.gov/38676839/> - Polaskey MT, Woolery-Lloyd H, Osborne D, Burnett P, Hanna D, Chovatiya R. When Patient Diversity Informs Formulation: Reimagining Treatment for Seborrheic Dermatitis. *Dermatol Ther (Heidelb)*. 2024 May;14(5):1071-1077. doi: 10.1007/s13555-024-01161-9. Epub 2024 Apr 27. PMID: 38676839; PMCID: PMC11116352. <https://doi.org/10.1007/s13555-024-01161-9>

• <https://pubmed.ncbi.nlm.nih.gov/36370336/> - Stein Gold L, Alonso-Llamazares J, Draelos ZD, Gooderham MJ, Kempers SE, Kircik LH, Lebwohl MG, Papp KA, Pariser DM, Toth DP, Yosipovitch G, Higham RC, Feng A, Berk DR. Effect of Roflumilast Cream (ARQ-151) on Itch and Itch-Related Sleep Loss in Adults with Chronic Plaque Psoriasis: Patient-Reported Itch Outcomes of a Phase 2b Trial. *Am J Clin Dermatol*. 2023 Mar;24(2):305-313. doi: 10.1007/s40257-022-00739-3. Epub 2022 Nov 12. PMID: 36370336; PMCID: PMC9968264. <https://doi.org/10.1007/s40257-022-00739-3>

• <https://pubmed.ncbi.nlm.nih.gov/38556093/> - Stein Gold L, Adam DN, Albrecht L, Alonso-Llamazares J, Ferris LK, Gooderham MJ, Hong HC, Kempers SE, Kircik LH, Lebwohl M, Loo WJ, Nahm WK, Papp KA, Stewart D, Toth DP, Zirwas M, Krupa D, Snyder S, Burnett P, Higham R, Berk DR. Long-term safety and effectiveness of roflumilast cream 0.3% in adults with chronic plaque psoriasis: A 52-week, phase 2, open-label trial. *J Am Acad Dermatol*. 2024 Mar 29:S0190-9622(24)00541-3. doi:

10.1016/j.jaad.2024.03.030. Epub ahead of print. PMID: 38556093. [https://www.jaad.org/article/S0190-9622\(24\)00541-3/fulltext](https://www.jaad.org/article/S0190-9622(24)00541-3/fulltext)

- <https://pubmed.ncbi.nlm.nih.gov/36422852/> - Thurston AW Jr, Osborne DW, Snyder S, Higham RC, Burnett P, Berk DR. Pharmacokinetics of Roflumilast Cream in Chronic Plaque Psoriasis: Data from Phase I to Phase III Studies. *Am J Clin Dermatol*. 2023 Mar;24(2):315-324. doi: 10.1007/s40257-022-00741-9. Epub 2022 Nov 24. PMID: 36422852; PMCID: PMC9968262. <https://doi.org/10.1007/s40257-022-00741-9>
- <https://pubmed.ncbi.nlm.nih.gov/37133856/> - Zirwas MJ, Draelos ZD, DuBois J, Kircik LH, Moore AY, Stein Gold L, Alonso-Llamazares J, Bukhalo M, Bruce S, Eads K, Green LJ, Guenther ST, Ferris LK, Forman SB, Kempers SE, Lain E, Lynde CW, Pariser DM, Toth DP, Yamauchi PS, Higham RC, Krupa D, Burnett P, Berk DR. Efficacy of Roflumilast Foam, 0.3%, in Patients With Seborrheic Dermatitis: A Double-blind, Vehicle-Controlled Phase 2a Randomized Clinical Trial. *JAMA Dermatol*. 2023 Jun 1;159(6):613-620. doi: 10.1001/jamadermatol.2023.0846. PMID: 37133856; PMCID: PMC10157502. <https://jamanetwork.com/journals/jamadermatology/fullarticle/2804569>
- <https://pubmed.ncbi.nlm.nih.gov/36809324/> - Lebwohl MG, Hebert AA, Gooderham MJ. Roflumilast Cream vs Vehicle Cream and Chronic Plaque Psoriasis-Reply. *JAMA*. 2023 Feb 21;329(7):595. doi: 10.1001/jama.2022.22649. PMID: 36809324. <https://jamanetwork.com/journals/jama/fullarticle/2801683>
- [https://www.jaad.org/article/S0190-9622\(24\)02140-6/fulltext](https://www.jaad.org/article/S0190-9622(24)02140-6/fulltext) - Gooderham, M., Bagel, J., Forman, S., et al. 2025. Patient-Reported Outcomes with Roflumilast Foam 0.3% in Individuals with Psoriasis of the Scalp and Body in the Phase 3 Trial. *SKIN The Journal of Cutaneous Medicine*. 9, 2 (Mar. 2025), s525. DOI: <https://doi.org/10.25251/skin.10.suppl.525>. <https://skin.dermsquared.com/skin/article/view/3265>
- <https://pmc.ncbi.nlm.nih.gov/articles/PMC11411450/> Simpson EL, et al. Roflumilast Cream, 0.15%, for Atopic Dermatitis in Adults and Children: INTEGUMENT-1 and INTEGUMENT-2 Randomized Clinical Trials. *JAMA Dermatol*. 2024 Nov 1;160(11):1161-1170. doi: 10.1001/jamadermatol.2024.3121. Erratum in: *JAMA Dermatol*. 2025 Apr 23. doi: 10.1001/jamadermatol.2025.1153. PMID: 39292443; PMCID: PMC11411450.
- https://jamanetwork.com/journals/jamadermatology/fullarticle/2823304#google_vignette
- <https://www.dermatologytimes.com/view/cosmetic-moisturizers-and-pharmaceutical-vehicles> - Zoe Diana Draelos, MD February 16, 2021 *Dermatology Times*, March 2021 (Vol. 42, No. 3) *Cosmetic Moisturizers and Pharmaceutical Vehicles*

*Kindly clearly label your files with company name and asset name.