Zoryve® (roflumilast) – New indication

- On May 22, 2025, Arcutis Biotherapeutics announced the FDA approval of Zoryve (roflumilast) topical foam, for the **treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older**.

- Zoryve topical foam is also approved for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

- Zoryve is also available as a topical cream and approved for the treatment of:

    - Plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.
    - Mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

- The approval of Zoryve foam for the new indication was based on two randomized, double-blind, vehicle-controlled studies (Trial ARRECTOR and Trial 204) in a total of 736 adult and pediatric patients 12 years of age and older with mild to severe plaque psoriasis of the scalp and body. Patients were randomized to Zoryve topical foam or vehicle foam. Primary endpoints were Scalp Investigator Global Assessment (S-IGA) and Body Investigator Global Assessment (B-IGA) treatment success.

    - In Trial ARRECTOR, S-IGA success was achieved in 66.4% and 27.8% of patients with Zoryve and vehicle, respectively (difference 37.1, 95% CI: 27.1, 47.1). B-IGA success was achieved in 45.5% and 20.1% of patients, respectively (difference 24.8, 95% CI: 15.0, 34.6).
    - In Trial 204, S-IGA success was achieved in 56.7% and 11.0% of patients with Zoryve and vehicle, respectively (difference 47.7, 95% CI: 37.9, 57.5). B-IGA success was achieved in 39.0% and 7.4% of patients, respectively (difference 32.4, 95% CI: 23.3, 41.6).

- The most common adverse reactions (≥ 1%) with Zoryve topical use for plaque psoriasis were headache, diarrhea, nausea, and nasopharyngitis.

- Zoryve topical foam is applied as a thin layer once daily to affected areas of body and/or scalp when they are not wet

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