

Zoryve™ (roflumilast) – New drug approval

- On July 29, 2022, [Arcutis Biotherapeutics announced](#) the [FDA approval](#) of [Zoryve \(roflumilast\)](#), for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.
- Psoriasis is a common, non-contagious, immune-mediated skin disease in which the majority of individuals develop “plaques,” or raised, red areas of skin covered with a silver or white layer of dead skin cells. Psoriatic plaques are often itchy and sometimes painful and can appear on any area of the body.
 - Psoriasis affects approximately 9 million people in the U.S.
- Zoryve is the first topical phosphodiesterase-4 inhibitor approved for the treatment of plaque psoriasis.
- The efficacy of Zoryve was established in two randomized, double-blind, vehicle-controlled trials (DERMIS-1 and DERMIS-2) that enrolled a total of 881 subjects with mild to severe plaque psoriasis. Patients received Zoryve or vehicle applied once daily for 8 weeks. The primary endpoint was the proportion of subjects who achieved Investigator’s Global Assessment (IGA) treatment success at week 8. Success was defined as a score of “Clear” (0) or “Almost Clear” (1), plus a 2-grade improvement from baseline.
 - In DERMIS-1, IGA success was seen in 41.5% of Zoryve treated patients vs. 5.8% of vehicle treated patients (Difference from vehicle: 39.7%; 95% CI: 32.4, 47.0).
 - In DERMIS-2, IGA success was seen in 36.7% of Zoryve treated patients vs. 7.1% of vehicle treated patients (Difference from vehicle: 29.5%; 95% CI: 21.5, 37.6).
- Zoryve is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).
- The most common adverse reactions ($\geq 1\%$) with Zoryve use were diarrhea, headache, insomnia, application site pain, upper respiratory tract infections, and urinary tract infections.
- Zoryve should be applied to affected areas once daily and rubbed in completely.
- Arcutis Biotherapeutics plans to launch Zoryve by mid-August 2022. Zoryve will be available as a 0.3% cream in 60-gram tubes.