Rx

The **first and only PDE4 inhibitor** indicated in the topical treatment of plaque psoriasis.*

QUESTIONS-ANSWERS

ABOUT NEW Pr ZORYVE™ roflumilast cream 0.3%

Introducing ZORYVE

- **Once-daily topical application**
- **Can be used on intertriginous areas**

What is ZORYVE indicated for?

For ages 12+

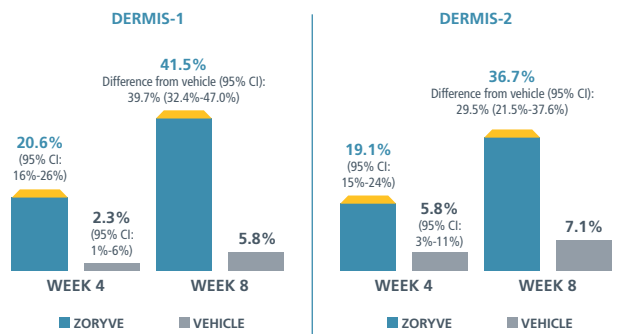
BOLDLY TAKING ON PLAQUE PSORIASIS

ZORYVE (roflumilast cream, 0.3%) is indicated for topical treatment of plaque psoriasis, including treatment of psoriasis in the intertriginous areas, in patients 12 years of age and older.[1]

What was the efficacy data for ZORYVE in clinical trials?

In the Phase 3 DERMIS-1 and DERMIS 2 studies, ZORYVE demonstrated efficacy at Week 8 in the topical treatment of plaque psoriasis.[1,2†] ZORYVE is only indicated in patients 12 years and older.[1]

Significantly more patients achieved IGA success at Week 8 in the ZORYVE group vs. vehicle[1,2‡]



7x more ZORYVE patients achieved IGA success than vehicle-treated patients (41.5% vs. 5.8% [difference from vehicle: 39.7%, 95% CI: 32.4%-47.0%])

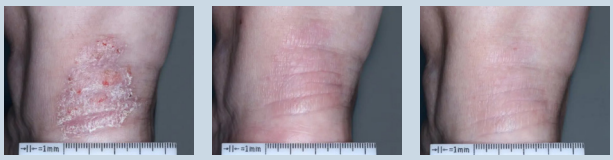
5.3x more ZORYVE patients achieved IGA success than vehicle-treated patients (36.7% vs. 7.1% [difference from vehicle: 29.5%, 95% CI: 21.5%-37.6%])

PDE4: phosphodiesterase-4 inhibitor; IGA: Investigator's Global Assessment; BSA: body surface area; I-IGA: intertriginous-IGA; CI: confidence interval OR: odds ratio.

* Comparative clinical significance has not been established.

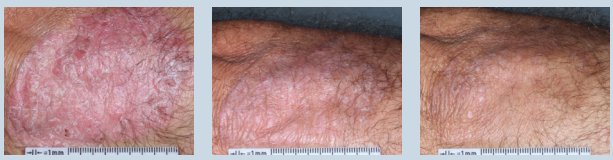
IGA success – heel and elbow photos: DERMIS-1 (ZORYVE n=286; vehicle n=153)

Heel§



Baseline IGA = 2 | Week 4 IGA = 0 | Week 8 IGA = 0

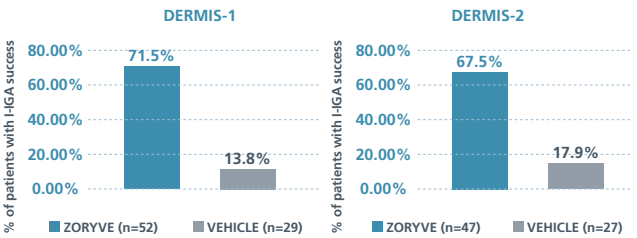
Elbow§



Baseline IGA = 3 | Week 4 IGA = 1 | Week 8 IGA = 0

§ Actual clinical trial patient. May not be reflective of the general population.

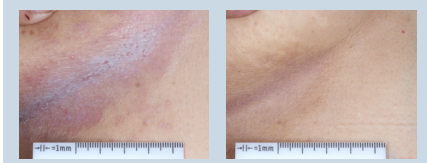
Significantly more patients with intertriginous area involvement achieved I-IGA success in the ZORYVE group vs. vehicle at Week 8 (secondary endpoint)[1¶]



66.5% difference in favour of ZORYVE vs. vehicle (95% CI: 47.1-85.8, $p<0.0001$)

51.6% difference in favour of ZORYVE vs. vehicle (95% CI: 29.3-73.8, $p<0.0004$)

Inframammary crease photos:§ DERMIS-1 (ZORYVE n=63; vehicle n=32)



Baseline I-IGA = 3 | Week 8 I-IGA = 0

§ Actual clinical trial patient. May not be reflective of the general population.

† DERMIS-1 and DERMIS-2 were Phase 3 randomized, double-blind, vehicle-controlled, multicentre studies (n=881) that evaluated ZORYVE over 8 weeks as a once-daily topical treatment for mild to severe plaque psoriasis (IGA of disease severity of 2-4 at baseline and an affected BSA of 2% to 20%). Subjects were randomized 2:1 to receive ZORYVE or vehicle applied to plaque psoriasis lesions (excluding scalp).

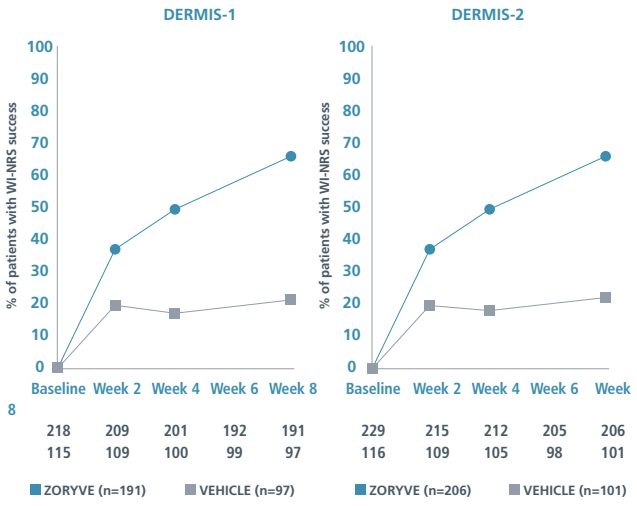
‡ IGA success was defined as clear or almost clear (IGA 0 or 1) and ≥ 2-grade IGA score improvement from baseline.

¶ I-IGA success was defined as clear or almost clear (I-IGA 0 or 1) and ≥ 2-grade I-IGA score improvement from baseline.

ARCUTIS BIOTHERAPEUTICS

REVIEWED BY PAAB

More ZORYVE patients achieved statistical significance in WI-NRS success vs. those receiving vehicle (secondary endpoint)[1¥]



At Week 8, 2.5x more ZORYVE patients demonstrated an improvement in itch intensity vs. vehicle-treated patients (67.5% vs. 26.8% [OR: 7.8, 95% CI: 3.9-15.9, *p*<0.0001])

At Week 8, 1.9x more ZORYVE patients demonstrated an improvement in itch intensity vs. vehicle-treated patients (69.4% vs. 35.6% [OR: 3.6, 95% CI: 2.1-6.2, *p*<0.0001])

The treatment difference at Week 2 was not statistically significant.

How is ZORYVE dosed?

ZORYVE is designed for simple administration.

Recommended dosing and application[1]

- Apply ZORYVE to affected areas once daily.
- Rub in completely.
- Wash hands after application unless hands are being treated.

ZORYVE is formulated with HYDRO**ARQ** TECHNOLOGY™£

STEROID-FREE PDE4 INHIBITOR

What is the safety profile of ZORYVE?

ZORYVE was generally well tolerated. ZORYVE is only indicated in patients 12 years and older.

Adverse reactions reported in ≥1% of patients treated with ZORYVE for 8 weeks in DERMIS-1 and DERMIS-2[1]

	ZORYVE (N=576) (%)	Vehicle (N=305) (%)
Gastrointestinal		
Diarrhea	18 (3.1)	0 (0.0)
Nausea	7 (1.2)	2 (0.7)
Infections and infestations		
Upper respiratory tract infection	6 (1.0)	1 (0.3)
Urinary trat infection	6 (1.0)	6 (1.0)
Nervous system disorders		
Headache	14 (2.4)	3 (1.0)
Psychiatric disorders		
Insomnia	8 (1.4)	2 (0.7)
Skin and subcutaneous tissue disorders		
Application site pain	6 (1.0)	1 (0.3)

- Observed discontinuation rates: 1.7% vs. 1.3% in DERMIS-1 and 0.3% vs. 1.3% in DERMIS-2 with ZORYVE and vehicle, respectively.[2]
- Reported rates of application site pain: 0.7% vs. 0.7% in DERMIS-1 and 1.4% vs. 0.0% in DERMIS-2 with ZORYVE and vehicle, respectively.[2]

Open-label extension studies

The adverse reaction profile was similar to that observed in vehicle-controlled studies among 594 patients who continued treatment with ZORYVE for up to 64 weeks.[1]

Conditions of use:
- The safety and efficacy data submitted in patients aged 12 to 17 years are very limited
- Safety and efficacy in patients <12 years have not been established

Contraindications:
- Patients with moderate to severe liver impairment (Child-Pugh B or C)

Relevant warnings and precautions:
- Topical use only, not for ophthalmic, oral, or intravaginal use
- Fertility
- Pregnant and breast-feeding women

For more information:
Please see the Product Monograph at http://arcutis.ca/zoryve-pm-hcp for important information on adverse reactions, drug interactions, and administration not discussed in this piece. The Product Monograph is also available by calling 1-844-692-6729.

References:
1. ZORYVE Product Monograph. Arcutis Canada, Inc. November 7, 2023.
2. Lebwohl MG 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.

Arcutis Canada, Inc.

WI-NRS: Worst Itch Numeric Rating Scale
¥ WI-NRS success was defined as a reduction of ≥ 4 points in patients with a WI-NRS score of 4 or higher at baseline.
£ Clinical significance unknown.

EnsembleIQ
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NEW Pr ZORYVE™ roflumilast cream 0.3%

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