



DR. JEFF C.H. DONOVAN

DERMATOLOGIST, SPECIALIZING IN HAIR LOSS

4370 Lorimer Road
Suite 334B
Whistler, BC, Canada
V8E 1A6

Tel: 604.283.1887

Fax: 604.648.9003

Email: office@donovanmedical.com

Web: www.donovanmedical.com

ZORYVE (Roflumilast 0.3 %) Cream **Information for Patients of Dr. Donovan**

What is ZORYVE?

This is a topical medication that is FDA and Health Canada approved to treat psoriasis. It blocks a specific pathway known as the phosphodiesterase pathway. Specifically, ZORYVE is a Phosphodiesterase-4 (PDE-4) Inhibitor.

What is ZORYVE formally approved for?

ZORYVE™ (roflumilast cream, 0.3%) is formally approved as a topical treatment of plaque psoriasis, including treatment of psoriasis in the intertriginous areas, in patients 12 years of age and older.

How often is the drug used?

The drug is applied once daily. After application, hands are to be washed.

What are the side effects of ZORYVE?

Side effects were evaluated in two Phase 3, multicenter, randomized, double-blind, vehicle-controlled trials (called DERMIS-1 and DERMIS-2). These trials enrolled a total of 881 subjects with mild to severe plaque psoriasis.

Side effects include diarrhea (3% vs 0 % placebo), nausea (1.2% vs 0.7% placebo), upper respiratory tract infections (1% vs 0.3% placebo), urinary tract infections (1% vs 0.7% placebo), headaches (2.4% vs 1.0% placebo), insomnia (1.4% vs 0.7% placebo), and application site pain (1% vs 0.3% placebo).

Diarrhea with roflumilast is generally limited to the first 2 weeks and resolves with continued treatment.

Weight loss was also seen in trials (4% vs 2.3% placebo in short term studies). By 1 year, 13 % of patients using roflumilast had more than 5% reduction in weight.

Among patients who use the drug even longer, side effects may become similar to placebo.

Who should not receive ZORYVE?

The medication should not be used by those with sensitivity to any of the ingredients in the medication, those who are pregnant or breastfeeding and pediatric patients under age 12.

