

Trade Name (generic)				
Rhofade (oxymetazoline) cream 1% for topical use				
Indications				
Oxymetazoline topical therapy is indicated for persistent facial erythema associated with rosacea in adults				
Dosage				
A pea-sized amount applied once daily to the entire face in a thin layer, avoiding the eyes and lips				
Background				
Oxymetazoline is an alpha1A adrenoceptor agonist and acts as a vasoconstrictor				
Efficacy				
The FDA approved once-daily oxymetazoline cream (1%) based on two identical, double-blind, vehicle-controlled clinical trials that randomized (1:1) predominantly female (79%) and Caucasian (90%) subjects (n=885) who were aged ≥18 years. Clinicians and subjects graded disease severity using a 5-point clinician erythema assessment (CEA) scale and a 5-point subject self-assessment (SSA) scale, respectively, on which subjects scored either “moderate” or “severe” on both scales. CEA and SSA were measured at 3, 6, 9, and 12 hours post-dose on Days 1, 15, and 29 of the 29-day study. Following is the primary endpoint data (proportions of subjects with ≥2-grade reduction in erythema from baseline on both the CEA and SSA measured at hours 3, 6, 9, and 12 on Day 29) for both trials:				
	Trial 1		Trial 2	
Time-point on Day 29	Oxymetazoline (n=222)	Vehicle (n=218)	Oxymetazoline (n=224)	Vehicle (n=221)
Hour 3	12%	6%	14%	7%
Hour 6	16%	8%	13%	5%
Hour 9	18%	6%	16%	9%
Hour 12	15%	6%	12%	6%
Safety				
Common adverse reactions: Application site dermatitis, pruritus, erythema, and pain; worsening inflammatory lesions of rosacea				
Warnings and precautions: Use cautiously in patients with cerebral or coronary insufficiency, Raynaud’s phenomenon, thromboangiitis obliterans, scleroderma, Sjögren’s syndrome, severe or unstable or uncontrolled cardiovascular disease, orthostatic hypotension, or uncontrolled hypertension or hypotension; may affect blood pressure and increase risk of angle closure glaucoma in patients with narrow-angle glaucoma; advise patients who have signs and symptoms of acute narrow-angle glaucoma or potentiation of vascular insufficiency and patients who have worsening cardiovascular disease, orthostatic hypotension, or uncontrolled hypertension or hypotension to seek medical care; use cautiously drugs such as beta-blockers, anti-hypertensives, and cardiac glycosides, as well as alpha1 adrenergic receptor antagonists and MAO inhibitors.				
Avoid use: Pediatric patients <18 years of age				
Evidence Gaps/Limitations				
No additional studies found to support evidence for use in the treatment of Oregon Health Plan (OHP) funded conditions or co-morbidities.				
Recommendation				
Restrict use for OHP-funded conditions through Prior Authorization.				
References				
1. Rhofade (oxymetazoline cream) [Prescribing Information]. Irvine, CA; Allergan, January 2017.				