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Azelaic Acid (Finacea Gel)

??? ??????: 30 ??????/?????? 2017

Overall, treatment related adverse events, including burning, stinging/tingling, dryness/tightness/ scaling, itching, and erythema/irritation/redness, were 19.4% (24/124) for FINACEA Gel (azelaic acid) , 15%, and 7.1% (9/127) for the active comparator gel at 15 weeks.

In two vehicle controlled, and one active controlled U.S. clinical studies, treatment safety was monitored in 788 patients who used twice daily FINACEA Gel, 15%, for 12 weeks (N=333) or for 15 weeks (N=124), or the gel vehicle (N=331) for 12 weeks.

Table 3: Cutaneous Adverse Events Occurring in ? 1% of Subjects in the Rosacea Trials by Treatment Group and Maximum Intensity*

	Vehicle N=331 (100%)			FINACEA Gel,15% N=457 (100%)			
	Severe	Moderate	Mild	Severe	Moderate	Mild	
	n=5	n=30	n=46	n=27	n=61	n=99	
	(2%)	(9%)	(14%)	(6%)	(13%)	(22%)	
Burning/stinging/tingling	2 (1%)	6 (2%)	8 (2%)	17(4%)	42 (9%)	71(16%)	
Pruritus	0 (0%)	6 (2%)	9 (3%)	5 (1%)	18 (4%)	29(6%)	
Scaling/dry skin/xerosis	1(< 1%)	14 (4%)	31(9%)	5 (1%)	10 (2%)	21(5%)	
Erythema/irritation	2 (1%)	4 (1%)	8 (2%)	2(< 1%)	7 (2%)	6 (1%)	
Contact dermatitis	0 (0%)	0 (0%)	1(< 1%)	0 (0%)	3 (1%)	2(<1%)	
Edema	0 (0%)	0 (0%)	3 (1%)	0 (0%)	2 (< 1%)	3 (1%)	
Acne	0 (0%)	0 (0%)	1(< 1%)	0 (0%)	1 (< 1%)	3 (1%)	

*Subjects may have > 1 cutaneous adverse event; thus, the sum of the frequencies of preferred terms may exceed the number of subjects with at least 1 cutaneous adverse event.

FINACEA Gel (azelaic acid) , 15%, and its vehicle caused irritant reactions at the application site in human dermal safety studies. FINACEA Gel (azelaic acid) , 15%, caused significantly more irritation than its vehicle in a cumulative irritation study. Some improvement in irritation was demonstrated over the course of the clinical studies, but this improvement might be attributed to subject dropouts. No phototoxicity or photoallergenicity were reported in human dermal safety studies.

In patients using azelaic acid formulations, the following additional adverse experiences have been reported rarely: worsening of asthma, vitiligo depigmentation, small depigmented spots, hypertrichosis, reddening (signs of keratosis pilaris), and exacerbation of recurrent herpes labialis.

).**PRECAUTIONS** Post-marketing safety—Skin: facial burning and irritation; Eyes: iridocyclitis on accidental exposure with FINACEA Gel, 15%, to the eye (see