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## Alitretinoin (Panretin)

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The safety of Panretin® (alitretinoin) gel has been assessed in clinical studies of 385 patients with AIDS-related KS. Adverse events associated with the use of Panretin® (alitretinoin) gel in patients with AIDS-related KS occurred almost exclusively at the site of application. The dermal toxicity begins as erythema; with continued application of Panretin® (alitretinoin) gel, erythema may increase and edema may develop. Dermal toxicity may become treatment-limiting, with intense erythema, edema, and vesiculation. Usually, however, adverse events are mild to moderate in severity; they led to withdrawal from the study in only 7% of the patients. Severe local (application site) skin adverse events occurred in about 10% of patients in the U.S. study (versus 0% in the vehicle control). Table 2 lists the adverse events that occurred at the application site with an incidence of at least 5% during the double-blind phase in the Panretin® (alitretinoin) gel-treated group and in the vehicle control group in either of the two controlled studies. Adverse events were reported at other sites but generally were similar in the two groups.

**TABLE 2: Adverse Events with an Incidence of at Least 5% at the Application Site in Either Controlled Study in Patients Receiving Panretin® (alitretinoin) Gel or Vehicle Control**

Adverse Event Term	Study 2		Study 1	
	Vehicle Gel (N=46 Pts. %)	Panretin® (alitretinoin) Gel (N=36 Pts. %)	Vehicle Gel (N=134 Pts. %)	Panretin® (alitretinoin) Gel (N=134 Pts. %)
<sup>1</sup> Rash	4	25	11	77
<sup>2</sup> Pain	4	0	7	34
<sup>3</sup> Pruritus	4	8	4	11
<sup>4</sup> Exfoliative dermatitis	0	3	2	9
<sup>5</sup> Skin disorder	0	0	1	8
<sup>6</sup> Paresthesia	7	22	0	3
<sup>7</sup> Edema	0	3	3	8

Includes Investigator terms:  
 Erythema, scaling, irritation, redness, rash, dermatitis<sup>1</sup>  
 Burning, pain<sup>2</sup>  
 Itching, pruritus<sup>3</sup>  
 Flaking, peeling, desquamation, exfoliation<sup>4</sup>  
 Excoriation, cracking, scab, crusting, drainage, eschar, fissure or oozing<sup>5</sup>  
 Stinging, tingling<sup>6</sup>  
 Edema, swelling, inflammation<sup>7</sup>