Geriatric Use

Inadequate information is available to assess safety and efficacy in patients age 65 years or older.

ADVERSE REACTIONS

The safety of Panretin® gel has been assessed in clinical studies of 385 patients with AIDS-related KS. Adverse events associated with the use of Panretin® 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® 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® 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® Gel or Vehicle Control

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

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

OVERDOSAGE

There has been no experience with acute overdose of Panretin® gel in humans. Systemic toxicity following acute overdosage with topical application of Panretin® gel is unlikely because of limited systemic plasma levels observed with normal therapeutic doses. There is no specific antidote for overdosage.

DOSAGE AND ADMINISTRATION

Panretin® gel should initially be applied two (2) times a day to cutaneous KS lesions. The application frequency can be gradually increased to three (3) or four (4) times a day according to individual lesion tolerance. If application site toxicity occurs, the application frequency can be reduced. Should severe irritation occur, application of drug can be temporarily discontinued for a few days until the symptoms subside.

Sufficient gel should be applied to cover the lesion with a generous coating. The gel should be allowed to dry for three to five minutes before covering with clothing. Because unaffected skin may become irritated, application of the gel to normal skin surrounding the lesions should be avoided. In addition, do not apply the gel on or near mucosal surfaces of the body.

A response of KS lesions may be seen as soon as two weeks after initiation of therapy but most patients require longer application. With continued application, further benefit may be attained. Some patients have required over 14 weeks to respond. In clinical trials, Panretin® gel was applied for up to 96 weeks. Panretin® gel should be continued as long as the patient is deriving benefit.

Occlusive dressings should not be used with Panretin® gel.

How Supplied

Panretin® gel is available in tubes containing 60 grams. Store at 25° C (77° F); excursions permitted to 15-30° C (59-86° F) [see USP Controlled Room Temperature].

Manufactured for: Ligand Pharmaceuticals Incorporated
San Diego, CA 92121

by: Stiefel Laboratories, Inc.
Coral Gables, FL 33134

NDC 64365-501-01

Ligand Part #3000101
Stiefel Part #80068 (Rev. 0598)

平成20(2008)年3月　発行

厚生労働科学研究費補助金

政策創薬総合研究事業

厚生労働省　エイズ治療薬研究班

国内未承認エイズ治療薬等を用いたＨＩＶ感染症治療薬及びＨＩＶ感染症至適治療法の開発に係る応用研究

平成１９年度　総括・分担研究報告書

主任研究者　福武　勝幸

事務局
〒160-0023　東京都新宿区西新宿　6-7-1
東京医科大学病院　臨床検査医学講座
電話　03-3342-6111