

**Intensity of Local Skin Reactions During 5-Fluorouracil Treatment Related to the Number of Actinic Keratosis Lesions: A Post-hoc, Exploratory Analysis**

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## Supplementary Materials

**Supplementary Table 1.** Severity of A) erythema, B) oedema, C) scaling, D) crusting, E) erosion, F) pruritus and G) stinging after 4 weeks of treatment for actinic keratosis with 5-fluorouracil 4% cream in patient groups categorised according to the number of actinic keratosis lesions at baseline (pooled safety populations from Study HD-FUP3B-048 and Study HD-FUP3B-049).

	Number of actinic keratosis lesions at baseline					
	<5 (N=27)	5–10 (N=157)	11–15 (N=83)	16–20 (N=50)	21–25 (N=32)	>25 (N=54)
Severity of erythema						
None	12.50	0.69	1.35	0	0	0
Mild	16.67	24.14	13.51	15.56	13.33	7.84
Moderate	45.83	46.90	44.59	35.56	40.00	41.18
Severe	25.00	28.28	40.54	48.89	46.67	50.98
Severity of oedema						
None	37.50	44.14	36.49	42.22	26.67	23.53
Mild	41.67	37.24	35.14	37.78	20.00	29.41
Moderate	16.67	15.86	22.97	17.78	40.00	33.33
Severe	4.17	2.76	5.41	2.22	13.33	13.73

Severity of scaling

None	25.00	15.17	9.46	2.22	6.67	1.96
Mild	25.00	40.00	39.19	33.33	16.67	23.53
Moderate	37.50	33.10	39.19	35.56	43.33	37.25
Severe	12.50	11.72	12.16	28.89	33.33	37.25

Severity of crusting

None	37.50	27.59	16.22	15.56	6.67	7.84
Mild	29.17	35.17	33.78	24.44	33.33	27.45
Moderate	25.00	23.45	33.78	42.22	33.33	31.37
Severe	8.33	13.79	16.22	17.78	26.67	33.33

Severity of erosions

None	50.00	46.21	32.43	28.89	26.67	33.33
Mild	16.67	31.03	37.84	31.11	23.33	19.61
Moderate	29.17	16.55	24.32	31.11	26.67	27.45
Severe	4.17	6.21	5.41	8.89	23.33	19.61

Severity of pruritus

None	41.67	29.66	16.22	8.89	13.33	19.61
Mild	41.67	37.24	44.59	31.11	33.33	29.41
Moderate	12.50	26.21	24.32	37.78	46.67	21.57

Severe	4.17	6.90	14.86	22.22	6.67	29.41
Severity of stinging						
None	33.33	36.55	16.22	8.89	10.00	17.65
Mild	41.67	24.83	36.49	22.22	33.33	19.61
Moderate	20.83	23.45	28.38	46.67	40.00	29.41
Severe	4.17	15.17	18.92	22.22	16.67	33.33

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Data are % of patients.

Local skin reactions were assessed at week 2 and week 4; week 4 data are shown here. Local skin reactions were graded as a visual average across all treated areas using a 4-point numerical scale: 0 (none; no evidence of reaction), 1 (mild; faintly detectable reaction), 2 (moderate; clearly distinguishable reaction) or 3 (severe; marked/extensive/bothersome reaction).