

The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Study No.: C2380329				
Title: An exploratory, observational, cohort study investigating commercially available treatments which may reduce the scab stage of recurrent herpes labialis (RHL)				
Rationale: The aim of this observational study is to determine if presently available topical preparations, that have a potential to impact on wound healing, can influence scab formation during RHL				
Phase: Not applicable				
Study Period: 6 Sep 2005 – 29 Nov 2005				
Study Design: Observational, partially randomized open-label, three cohort study				
Centres: Single Center, United Kingdom				
Indication: Recurrent herpes labialis				
Treatment: All subjects entered the study already treating their cold sore with acyclovir cream. Once the cold sore had ulcerated, subjects in Cohort 1 were randomly assigned to either acyclovir or hyaluronan. For Cohorts 2 and 3, no randomization took place. Instead, once their cold sore had ulcerated, all subjects transferred from acyclovir to either polysaccharide gel or hydrogel depending upon whether they entered the study at Cohort 2 or 3. Treatment was applied topically 5x daily in Cohort 1, and 3x daily in Cohorts 2 and 3, for up to 10 days.				
Objectives: To investigate the impact of three currently available topical products on the wound healing process of RHL such that the "scab" is either reduced or modified in a way that improves healing and/or symptoms.				
Primary Outcome/Efficacy Variable: Observational assessment of ulcerating cold sore lesions in order to assess the impact of the test products on the appearance and size of the scab. Size of lesion, calculated by width*height of scab, from day of ulceration to day completely healed, up to day 10 or censored.				
Secondary Outcome/Efficacy Variable: None				
Statistical Methods: As this was an exploratory, observational study, no formal statistical testing was performed. Efficacy data were listed and summarized using appropriate descriptive statistics.				
Study Population: Recurrent herpes labialis sufferers				
	aciclovir	hyaluronan	polysaccharide	hydrogel
-Number of Subjects:	9	9	9	9
Planned, N	9	9	9	9
Completed, n (%)	7	9	9	9
Total Number Subjects Withdrawn, N (%)	2	0	0	0
Withdrawn due to Adverse Events n (%)	0	0	0	0
Withdrawn due to Lack of Efficacy n (%)	0	0	0	0
Withdrawn for other reasons n (%)	2	0	0	0
	aciclovir	hyaluronan	polysaccharide	hydrogel
Demographics				
N (ITT)	9	9	9	9
Females: Males	7:2	5:4	9:0	7:2
Mean Age, years (SD)	38.9 (10.47)	34.8 (12.23)	33.0 (8.89)	33.4 (12.60)
Caucasian, n (%)	9 (100)	8 (88.9)	9 (100)	9 (100)
Primary Efficacy Results: Median lesion size (mm ²)				
Time at Post Vesicle/Ulcer Stage	aciclovir	hyaluronan	polysaccharide	hydrogel
Day 0 (lesion ulcerated)	42.5 (n=8)	35.0 (n=9)	70.0 (n=9)	36.0 (n=9)
Day 1	36.5 (n=8)	25.0 (n=9)	42.0 (n=9)	25.0 (n=9)
Day 2	35.0 (n=7)	30.0 (n=8)	30.5 (n=8)	20.0 (n=9)
Day 3	15.0 (n=5)	25.0 (n=7)	25.0 (n=7)	16.0 (n=8)
Day 4	10.0 (n=4)	23.0 (n=6)	12.5 (n=6)	9.0 (n=7)
Day 5	10.0 (n=2)	15.0 (n=5)	20.0 (n=4)	9.0 (n=5)
Day 6	0.0 (n=2)	7.5 (n=4)	8.0 (n=4)	0.0 (n=4)
Day 7	--- (n=0)	0.0 (n=1)	0.0 (n=2)	0.0 (n=0)

Safety Results: On-therapy AEs (on or after date of ulceration, which is the start date of study medication, up to resolution or end of study)				
	aciclovir N=9	hyaluronan N=9	polysaccharide N=9	hydrogel N=9
Subjects with any AE(s), n(%)	0	3 (33.3)	0	1 (11.1)
Pain	0	3	0	0
Ill-defined disorder	0	0	0	1
Serious Adverse Events - On-Therapy n (%)				
	aciclovir N=9	hyaluronan N=9	polysaccharide N=9	hydrogel N=9
Subjects with non-fatal SAEs, n (%)	0	0	0	0
Subjects with fatal SAEs, n (%)	0	0	0	0

Conclusion:

All test products were well tolerated. The findings will be evaluated to determine whether further investigation in this patient population is warranted.

Publications: None planned.