

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.

<b>Study No.:</b> C2380329				
<b>Title:</b> An exploratory, observational, cohort study investigating commercially available treatments which may reduce the scab stage of recurrent herpes labialis (RHL)				
<b>Rationale:</b> 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				
<b>Phase:</b> Not applicable				
<b>Study Period:</b> 6 Sep 2005 – 29 Nov 2005				
<b>Study Design:</b> Observational, partially randomized open-label, three cohort study				
<b>Centres:</b> Single Center, United Kingdom				
<b>Indication:</b> Recurrent herpes labialis				
<b>Treatment:</b> 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.				
<b>Objectives:</b> 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.				
<b>Primary Outcome/Efficacy Variable:</b> 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.				
<b>Secondary Outcome/Efficacy Variable:</b> None				
<b>Statistical Methods:</b> As this was an exploratory, observational study, no formal statistical testing was performed. Efficacy data were listed and summarized using appropriate descriptive statistics.				
<b>Study Population:</b> Recurrent herpes labialis sufferers				
	<b>aciclovir</b>	<b>hyaluronan</b>	<b>polysaccharide</b>	<b>hydrogel</b>
-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
	<b>aciclovir</b>	<b>hyaluronan</b>	<b>polysaccharide</b>	<b>hydrogel</b>
<b>Demographics</b>				
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)
<b>Primary Efficacy Results:</b> Median lesion size (mm <sup>2</sup> )				
<b>Time at Post Vesicle/Ulcer Stage</b>	<b>aciclovir</b>	<b>hyaluronan</b>	<b>polysaccharide</b>	<b>hydrogel</b>
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)

<b>Safety Results: On-therapy AEs</b> (on or after date of ulceration, which is the start date of study medication, up to resolution or end of study)				
	<b>aciclovir N=9</b>	<b>hyaluronan N=9</b>	<b>polysaccharide N=9</b>	<b>hydrogel N=9</b>
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
<b>Serious Adverse Events - On-Therapy n (%)</b>				
	<b>aciclovir N=9</b>	<b>hyaluronan N=9</b>	<b>polysaccharide N=9</b>	<b>hydrogel N=9</b>
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.