

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	10
Adults (18-64 years)	15
From 65 to 84 years	0
85 years and over	0

End points

End points reporting groups

Reporting group title	Single arm (open label study)
Reporting group description: N-ACETYL-GED-0507-34-LEVO GEL 5%	
Subject analysis set title	Safety population
Subject analysis set type	Safety analysis
Subject analysis set description: Safety population: subjects who took at least one dose of investigational product and had at least one post-dose safety assessment.	

Primary: Safety endpoint

End point title	Safety endpoint ^[1]
End point description: The primary objective of the study was to determine local and systemic safety and tolerability of N-Acetyl-GED-0507-34-Levo after 12 weeks repeated daily exposures to 5% gel in patients with facial acne.	
End point type	Primary
End point timeframe: 12 weeks	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: DESCRIPTIVE STATISTIC (FREQUENCY TABLES) IS PROVIDED

End point values	Single arm (open label study)	Safety population		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	25	25		
Units: TEAEs related to study drug	3	3		

Statistical analyses

No statistical analyses for this end point

Headache subjects affected / exposed occurrences (all)	3 / 25 (12.00%) 3		
Gastrointestinal disorders Gastroenteritis subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2		
Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2		
Skin and subcutaneous tissue disorders Application site drynes subjects affected / exposed occurrences (all)	6 / 25 (24.00%) 6		
Infections and infestations Influenza subjects affected / exposed occurrences (all)	4 / 25 (16.00%) 4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

in the interpretation of the results the main limits of this study must be considered: a) open study design; b) absence of control group; c) relatively small size of the three study groups; d) study duration limited to 12 weeks.

Notes: