Non-interventional Results Summary

Study Number: 300098
Title: A Post-hoc Analysis of Study Data Obtained From China 1.16% And 2.32% Study To Evaluate 'Time To Onset Of Pain Relief' In Ankle Sprain Patients
Sponsor: Haleon Sponsored
Study Center: Not applicable
Analysis Start: 28 Apr 2023
Analysis End: 25 Jun 2023
Product / Medicine: Diclofenac diethylamine (DDEA)
Rationale: There is a general consumer perception that Topical Gels act slowly and provide delayed pain relief. This perception is driven by a data gap on speed of onset of pain relief for Voltaren topical formulations. The current study was performed to address this gap and investigate the current claims, potential opportunities to re-use the data for generating new claims on Speed of Onset/Time to Onset of Pain relief. The main purpose of this study was to characterize 'Time to Onset of Pain Relief' for Voltaren 1.16 percent (%) and Voltaren 2.32% gel in participants experiencing ankle sprain.
Phase: N/A
Study Period: 28 Apr 2023 to 25 Jun 2023
Study Design: The pain relief data generated from previous study 211206 (A randomized, double blind, multi center, active-controlled, 2 treatment arm, parallel group non inferiority study to evaluate the efficacy and safety of diclofenac diethylamine 2.32% gel applied twice daily versus diclofenac diethylamine 1.16% gel applied four times daily for one week in subjects with acute ankle sprain) was used to analyze the data for 'Time to onset of pain relief' after application of diclofenac diethylamine gel.
Actual Enrolment: Not applicable
Study Population: Participants for this analysis were considered from previous study 211206, who had experienced acute Grade I-II sprain of the ankle within the past 24 hours and experienced pain on movement (POM) of at least 50 millimetre (mm) on a 100 mm Visual Analogue Scale (VAS).
Study Investigators/Centers: Not Applicable
Data Source: Study 211206
Indication(s): Pain
Study Objectives: To characterize Time to Onset of Pain Relief for Voltaren 1.16 % and Voltaren 2.32 % gel in participants experiencing ankle sprain.
Study Exposures, Outcomes: Primary Endpoint: 1. Time to Onset of Pain Relief
Data Analysis Methods: The participant level data from study 211206 was used. Data was available for Spontaneous Pain relief that was collected every 2+/-0.5 hours on Day 1 and Day 5. Time to Onset of Pain relief was based on Survival (time to event) analysis: Spontaneous pain relief was assessed in the diary on a 5-point categorical scale. For definition of pain relief, a shift in one category on a scale 0 (no relief) to 4 (complete relief) (towards improved pain relief that is, either 0 to 1,2,3,4 or 1 to 2,3,4 or 2 to 3,4 or 3 to 4) from baseline was considered. Proportion of participants who achieved pain relief at each time point were considered for analysis. Median time to event and associated 95% confidence intervals were calculated using formulas found at PROC LIFETEST: Product-Limit Method: SAS/STAT(R) 9.2 User's Guide, Second Edition.

Limitations: Not Applicable

Study Results:

Participant Flow: This section is not applicable for this post-hoc analysis.

Demographics/Baseline Characteristics: This section is not applicable for this post-hoc analysis.

Primary Outcome Results:

1. Time to Onset of Pain relief for Voltaren DDEA 2.32% Gel and DDEA 1.16% Gel
   Unit of measure: hours

	Voltaren DDEA Gel 2.32%	**Voltaren DDEA Gel 1.16%**
Intent-to-treat (randomized) population	n=150	n=152
Median (95% Confidence Interval)	4.0 (4.0 to 6.0)	4.0 (4.0 to 6.0)
Per protocol population	n=122	n=128
Median (95% Confidence Interval)	4.0 (4.0 to 6.0)	4.0 (4.0 to 6.0)

	Voltaren DDEA Gel 2.32% + Voltaren DDEA Gel 1.16%
Intent-to-treat (randomized) population	n=302
Median (95% Confidence Interval)	4.0 (4.0 to 6.0)
Per protocol population	n=250
Median (95% Confidence Interval)	4.0 (4.0 to 6.0)

Safety Results: This section is not applicable for this post-hoc analysis.

Conclusion: The findings of this post-hoc analysis indicated that the median time to onset of pain relief for both Voltaren 1.16% four times daily (QID) and 2.32% twice daily (BID) formulations was 4 hours. The results were consistent across Intent-to-treat (ITT) and Per protocol (PP) populations. ITT population included all randomized participants. PP population included participants from the ITT population who had at least 1 postbaseline POM VAS assessment and who did not have any major protocol deviations (which were not affecting primary efficacy endpoint).