Non-interventional Results Summary

Study Number: 300099
Title: Post-hoc Analysis of Data Obtained from China 1.16% and 2.32% Study to Evaluate Relationship Between Treatment Compliance and Pain Relief After 5 Days in Ankle Sprain Patients
Sponsor: Haleon
Study Center: Not applicable
Analysis Start Date: 26-Apr-2023
Analysis Completion Date: 10-Aug-2023
Product / Medicine: Diclofenac diethylamine (DDEA)
Rationale: The results of the recently concluded study in China (Study Number 211206) have shown that after 5 days of treatment, 2 application per day, participants reach maximum pain relief. The purpose of this post-hoc analysis was to evaluate the relationship between compliance to treatment and pain relief after 5 days of treatment.
Phase: Not applicable
Study Period: 26-Apr-2023 to 10-Aug-2023
Study Design: This was a post-hoc analysis of data obtained from previously conducted study 211206. It was a phase III, randomized, double-blind, multicentre, active-controlled, 2-treatment arm, parallel group, non-inferiority study to evaluate the efficacy and safety of DDEA 2.32 percent (%) gel applied twice daily (BID) versus DDEA 1.16% gel applied four times daily (QID) for 1 week in participants with acute ankle sprain. Eligible participants were randomized as soon as possible after the injury. Participants who met all the inclusion criteria and none of the exclusion criteria were randomized in a 1:1 ratio to one of the 2 treatment arms.
Actual Enrolment: Not applicable
Study Population: Participants from previous study 211206 were considered, who had experienced an 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: Data from previously conducted study 211206
Indication(s): Pain
Study Exposures, Outcomes: **Primary Endpoint:** **1.** Percentage of Participants Experiencing Pain Relief and Compliance at Day 5 Compared to Baseline
Data Analysis Methods: No cause-effect relationship or no statistical tests were performed. A contingency table to present frequency (n), percent, row percent and column percent of change from baseline in pain relief and compliance categories by treatments was produced.
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. Frequency of Participants Experiencing Pain Relief and Compliance at Day 5 Compared to Baseline Unit of measure: Percentage of participants

Population: Per protocol population			
DDEA 1.16% Gel QID			
Compliance	**Any Relief**	**No Relief**	**Total**
Good	109 (89.3%)	6 (4.9%)	115 (94.3%)
Moderate/Poor	6 (4.9%)	1 (0.8%)	7 (5.7%)
Total	115 (94.3%)	7 (5.7%)	122 (100%)
DDEA 2.32% Gel BID			
Compliance	**Any Relief**	**No Relief**	**Total**
Good	108 (90.0%)	8 (6.7%)	116 (96.7%)
Moderate/Poor	4 (3.3%)	0 (0%)	4 (3.3%)
Total	112 (93.3%)	8 (6.7%)	120 (100%)
DDEA 1.16% Gel QID + DDEA 2.32% Gel BID			
Compliance	**Any Relief**	**No Relief**	**Total**
Good	217 (89.7%)	14 (5.8%)	231 (95.5%)
Moderate/Poor	10 (4.1%)	1 (0.4%)	11 (4.5%)
Total	227 (93.8%)	15 (6.2%)	242 (100%)
Safety Results: This section is not applicable for this post-hoc analysis.			
Conclusion: **1.** While the study findings showed no cause-effect relationship, this analysis confirmed that most participants with good compliance achieved at least some or any pain relief at day 5 in both treatment groups. **2.** Overall, the analysis concluded 'Participants with good compliance to treatment have pain relief after 5 days.			