Non-interventional Study Protocol 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 Centre: Not applicable
Study Start Date: 28 Apr 2023
Study Completion Date: 25 Jun 2023
Phase: N/A
Indication(s): Pain
Product / Medicine: Diclofenac diethylamine (DDEA)
Brief Summary: The main purpose of this study is to characterize Time to Onset of Pain Relief for Voltaren 1.16 percent (%) and Voltaren 2.32 % gel in participants experiencing ankle sprain.
Planned Enrolment: Not applicable
Number of Groups/Cohorts: 2
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) will be used to analyze the data for 'Time to onset of pain relief' after application of diclofenac diethylamine gel.
Study Population: Participants for this analysis will be 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 of at least 50 millimetre (mm) on a 100 mm Visual Analogue Scale.
Product Evaluated: Voltaren
Objectives: To characterize Time to Onset of Pain Relief for Voltaren 1.16 % and Voltaren 2.32 % gel in participants experiencing ankle sprain.
Data Analysis Methods: The participant level data from study 211206 will be used. Data is available for Spontaneous Pain relief that was collected every 2+/-0.5 hours on Day 1 and Day 5. 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 will be considered. Proportion of participants who achieve pain relief at each time point will be considered for analysis. Median time to event and associated 95% confidence intervals will be calculated using formulas found at PROC LIFETEST: Product-Limit Method: SAS/STAT(R) 9.2 User's Guide, Second Edition.
Primary Outcome: Time to Onset of Pain relief for Voltaren DDEA 2.32% Gel and DDEA 1.16% Gel