Non-interventional Study Protocol Summary

Study Number: 300099
Title: A Post-hoc Analysis of Data Obtained from China 1.16% and 2.32% Study to Evaluate Relationship Between Treatment Compliance and Pain Relief in Ankle Sprain Patients
Sponsor: Haleon
Study Centre: Not applicable
Analysis Start Date: 26-Apr-2023
Analysis Completion Date: 10-Aug-2023
Phase: Not Applicable
Indication(s): Pain
Product / Medicine: Diclofenac diethylamine (DDEA)
Brief Summary: 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 is to evaluate the relationship between compliance to treatment and pain relief after 5 days of treatment.
Planned Enrolment: Not applicable
Number of Groups/Cohorts: 2
Study Design: This will be the 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.
Study Population: Participants from previous study 211206 will be 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).
Product Evaluated: DDEA 2.32% gel and DDEA 1.16% gel
Objective: **1.** To evaluate relationship between compliance to treatment and pain relief after 5 days of treatment.
Data Analysis Methods: No cause-effect relationship or no statistical tests will be 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 will be produced.
Primary Outcome: **1.** Change from Baseline in Pain Relief at Day 5