

Enrollment

Assessed for eligibility (n=1252)

Excluded (n=469)

- Inclusion/exclusion criteria (n=416)
- Refused to participate (n=53)

Randomized (n=783)

Diclofenac
Sodium 1% Gel

Vehicle

Allocation

Allocated to receive diclofenac sodium 1% gel (n=400)
Received allocated intervention (n=400)

Allocated to receive vehicle gel (n=383)
Received allocated intervention (n=383)

Follow-up

Completed treatment (n=354)
Discontinued treatment (n=46)
 Adverse events (n=19)
 Lack of efficacy (n=11)
 Withdrew consent (n=8)
 Other (n=8)

Completed treatment (n=347)
Discontinued treatment (n=36)
 Lack of efficacy (n=17)
 Adverse events (n=9)
 Withdrew consent (n=7)
 Other (n=3)

Primary
Analysis

Evaluated for efficacy (n=400)

Evaluated for efficacy (n=383)

Post Hoc
Analysis

Population for pooled analysis (n=783)