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
Allocated to receive diclofenac sodium 1% gel (n=400)
Received allocated intervention (n=400)
Completed treatment (n=354)
Discontinued treatment (n=46)
Adverse events (n=19)
Lack of efficacy (n=11)
Withdrew consent (n=8)
Other (n=8)

Vehicle
Allocated to receive vehicle gel (n=383)
Received allocated intervention (n=383)
Completed treatment (n=347)
Discontinued treatment (n=36)
Lack of efficacy (n=17)
Adverse events (n=9)
Withdrew consent (n=7)
Other (n=3)

Evaluated for efficacy (n=400)
Evaluated for efficacy (n=383)

Population for pooled analysis (n=783)

Primary Analysis

Post Hoc Analysis

Follow-up

Allocation