HALEON

A Prospective Real-World Evidence Study Evaluating the Effects of Topical Diclofenac Gel Use on Mobility and Quality of Life in Subjects with Knee Osteoarthritis (OA) pain

Study Overview

Prospective, open-label, real-world, multi-country (EU and US)

196 adults with mild-to-moderate knee osteoarthritis

3 weeks of topical diclofenac use

Monitoring using ActiGraph (research-grade wearable)

Treatment Arms: Diclofenac Gel Dosing Groups

1%	1.16%	2.32%
(n = 39)	(n = 39)	(n = 118)

Compliance

The mean study treatment compliance was similar across all the three treatment groups of diclofenac gel (1% gel = 86.95%, 1.16% gel = 87.42%, and 2.32% gel = 88.75%)

ActiGraph wear compliance was high (≥ 20 hours/day threshold applied)

Endpoints

Primary

Change from baseline in average daily MVPA minutes/day measured by ActiGraph

Secondary

Objective (wearable-derived):
- Daily step count
- Sedentary/non-sedentary time ratio
- Gait speed and cadence
- Morning stiffness indices

Subjective (validated scales):
- WOMAC (pain, stiffness, function)
- NRS pain score
- Quality of life (EQ-5D-5L)

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Results and Clinical Interpretation

Primary Outcome: Mean daily MVPA (minutes/day)

Physical Activity Outcomes: MVPA

- **Baseline MVPA Levels:** 249.2 (92.99) minutes

Weekly MVPA During the Study Period

The mean (SD) average minutes of MVPA at subsequent time points were as follows:

- **Week 1:** 263.4 (101.87) minutes
- **Week 2:** 259.9 (104.61) minutes
- **Week 3:** 248.4 (104.60) minutes

Overall MVPA During the Treatment Period

- **Week 1 to Week 3:** 257.8 (99.30), which was higher than the baseline value of 249.2 (92.99)
- A statistically significant improvement in average minutes of MVPA over time was observed as measured by ActiGraph ($P < 0.001$).

Change in MVPA From Baseline

The mean (SD) change from baseline in average minutes of MVPA was:

- **Week 1:** 14.2 (53.54) minutes
  - LS mean: 15.6 (95% CI: 8.3, 22.8), $P < 0.001$
- **Week 2:** 10.7 (60.93) minutes
  - LS mean: 13.0 (95% CI: 5.2, 20.9), $P = 0.001$
- **Week 3:** −0.8 (71.08) minutes
  - LS mean: 2.1 (95% CI: −7.1, 11.3), $P = 0.653$

Clinically observed improvements in pain and motility

43%
felt relief while walking by Week 3

56%
climbed more stairs by Week 3

53%
showed improvement in stiffness by Week 3

72%
reported better mobility by Week 3

Overall, average minutes of MVPA increased significantly during the treatment period at week 1 and week 2 compared with baseline.

Secondary Outcomes

A Daily Steps

- **Week 1:** +602 steps/day vs. baseline ($P = 0.001$)
- **Week 2:** +323 steps/day ($P = 0.040$)

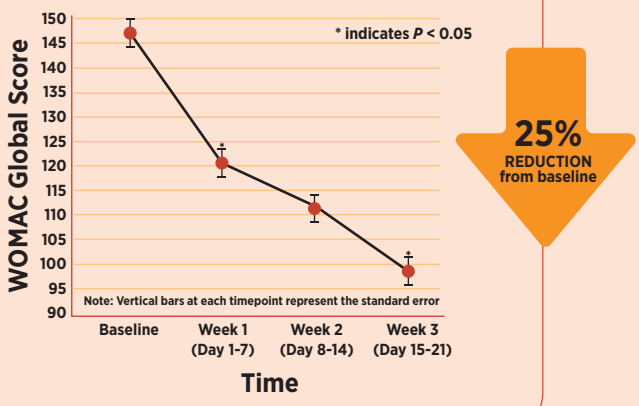
B Sedentary vs. Non-Sedentary Ratio

- Overall improvement across time ($P = 0.030$)
- Significant shift toward greater active time by week 3

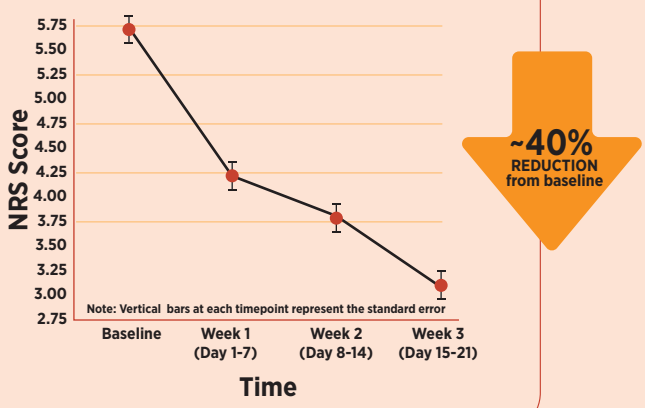
C Gait & Morning Stiffness

- Favorable trends in gait speed and cadence
- Reduction in morning stiffness indices over time

Significant Improvement Across Pain, Stiffness, and Physical Function Within 3 Weeks



Pain Scores Declined Steadily, Showing Visible, Real-World Recovery



Change From Baseline in Health-Related Quality of Life EQ-5D-5L

- EQ-5D-5L score during week 1 to week 3, was higher when compared with baseline with EQ-5D-5L score being statistically significantly higher at week 1, week 2 and week 3 vs. baseline.

Safety Profile

No serious or fatal AEs	No withdrawals due to AEs	All events mild-to-moderate none related to study treatment

Conclusion

- Marked improvements in MVPA and daily step count were observed during the first two weeks of treatment.
- Pain, stiffness, and physical function demonstrated strong and consistent gains as captured by WOMAC and NRS assessments.
- Improved daytime alertness and overall quality of life, as demonstrated by better KSS and EQ-5D-5L scores.
- A favorable safety profile, with no serious AEs reported and all TEAEs being mild-to-moderate.

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Abbreviations: TEAEs: Treatment-emergent adverse events; KSS: Karolinska Sleepiness Scale; EQ-5D-5L: EuroQol 5 dimensions 5 levels; WOMAC: Western Ontario and McMaster Universities Arthritis Index; NRS: Numerical rating scale; MVPA: Moderate-to-Vigorous Physical Activity; AEs: Adverse events; SD: Standard deviation; EU: European Union; US: United States.

Reference: Data on file