Khapregesic®: Redefining Menstrual Relief

CLINICAL RESEARCH AUSTRALIA

Clinical Trial Insights

An examination into the safety and efficacy of Khapregesic®, a Khaya senegalensis preparation, on pain, physical and emotional wellbeing in women experiencing menstrual distress: a randomised, double-blind, placebo-controlled trial.

"Khapregesic® represents a transformative advancement in pharmaceutical medications challenging the efficacy of traditional pain drugs such as paracetamol, ibuprofen, and other NSAIDs whilst also alleviating the psychological distress linked to severe menstrual symptoms.

This is the first time that a menstrual treatment has been developed that addresses both the physical and mental challenges faced by millions of women on a monthly basis.

These unprecedented clinical trial results and the number of women affected globally, positions Khapregesic® among the world's most advanced medical discoveries of our time." Clinical Trial Sponsor[1]

Key Findings: Khapregesic® vs Placebo

Pain: 136% reduction
Pain drug usage: reduced by 90%

Physical wellbeing: 70% improvement
(eg. Fatigue, insomnia, etc.)

Psychological wellbeing: 196% improvement
(eg. Aggression, mood swings, impulsiveness, anxiety, etc)

Quality of Life: Social Functioning 300% improvement
(eg. Reduced days off from work/school, increased days of exercise and other social activities)

Safety: All blood markers within normal limits and NO treatment related adverse reactions
(on a dosage 3 times currently recommended)

1 Indication Studied

Menstrual pain and distress, Safety dosage and duration.

2 Participants

Healthy females aged between 18-50 actively experiencing severe menstrual pain and distress at/or before ovulation and/or period bleed Randomised participants who took at least one treatment dose = 84 (Khapregesic® = 44, Placebo = 40) Duration between menstrual periods 21-35 days averaging 28 days, dosing daily Khapregesic® dose of 3 grams per day (2 X 500mg tablets, 3 times per day at 6 hourly intervals)

3 Efficacy Results

Pain Score - Excellent
The Khapregesic® group experienced 136% more pain relief/reduction than the placebo group[2] Participants in the Khapregesic® group reported a significant reduction in pain drug usage by 90%[3]

Physical Score - Excellent
The Khapregesic® group experienced 70% greater improvement in physical wellbeing than the placebo group[4]. This category includes items such as poor coordination, breast tenderness, fatigue, insomnia, etc.

Psychological Score - Excellent
The Khapregesic® group experienced 2 times (196%) greater improvement in psychological wellbeing than the placebo group[5] and 3 times (300%) greater improvement in Social Functioning than the placebo group[6]. This category includes items such as anxiety, mood swings, depression, crying, aggression, needing to take days off from work or school, limiting social activities and exercise.

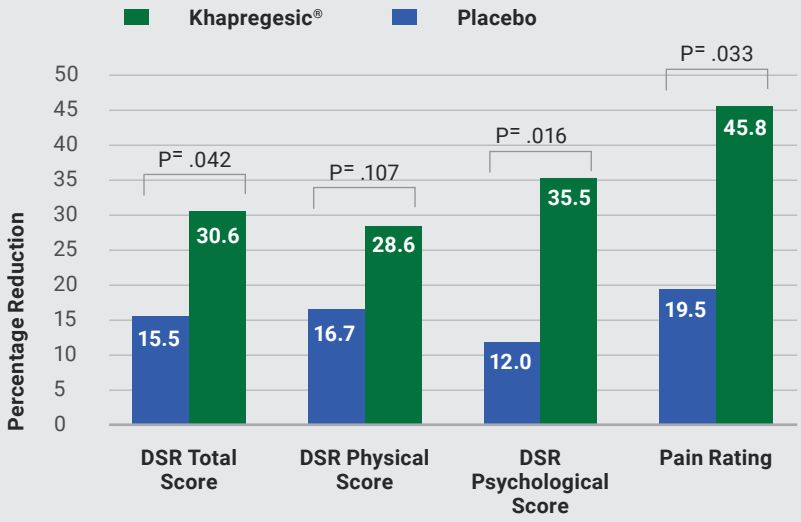

Figure 2: Percentage Change in Mean Self-Ratings from Menstrual Period 1 to Menstrual Period 2 (FAS)

4 Safety Results

Safety Score - Excellent
Complete blood count, liver and renal function revealed Khapregesic® had no significant effect on all blood markers which were all within normal limits. Tolerability of taking 6 tablets per day for 28-35 days was high with 98% of participants reporting good to excellent tolerability.

The number of Khapregesic® participants with NO treatment related adverse reactions was 91% (vs 82% in the placebo group).

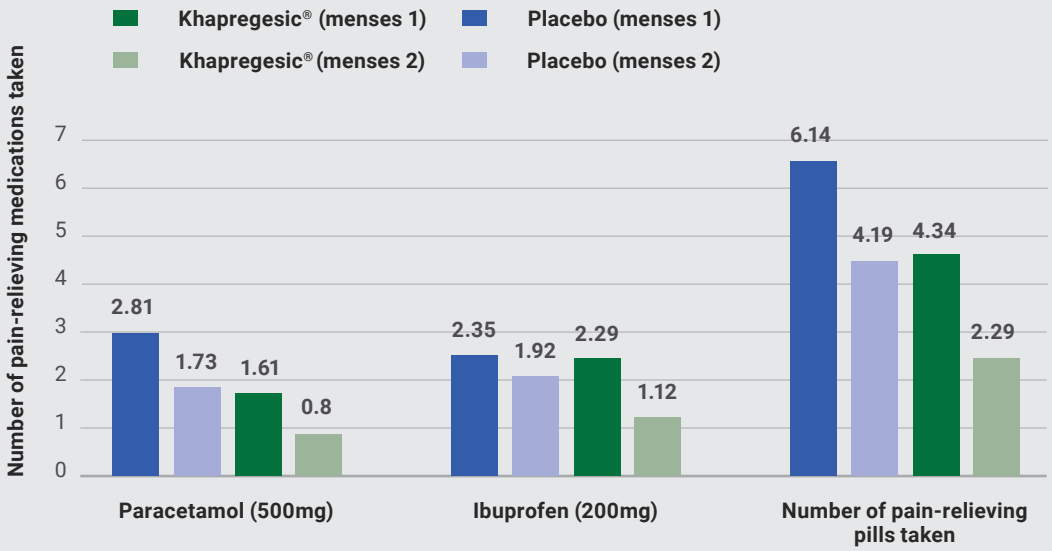

Figure 4: Number of pain-relieving medications taken during menses 1 and menses 2 (FAS)

5 Quality of Life Results

Quality of Life Score - Excellent
All results are positive vs. the placebo. Standouts are Social functioning, Pain and Emotional wellbeing.

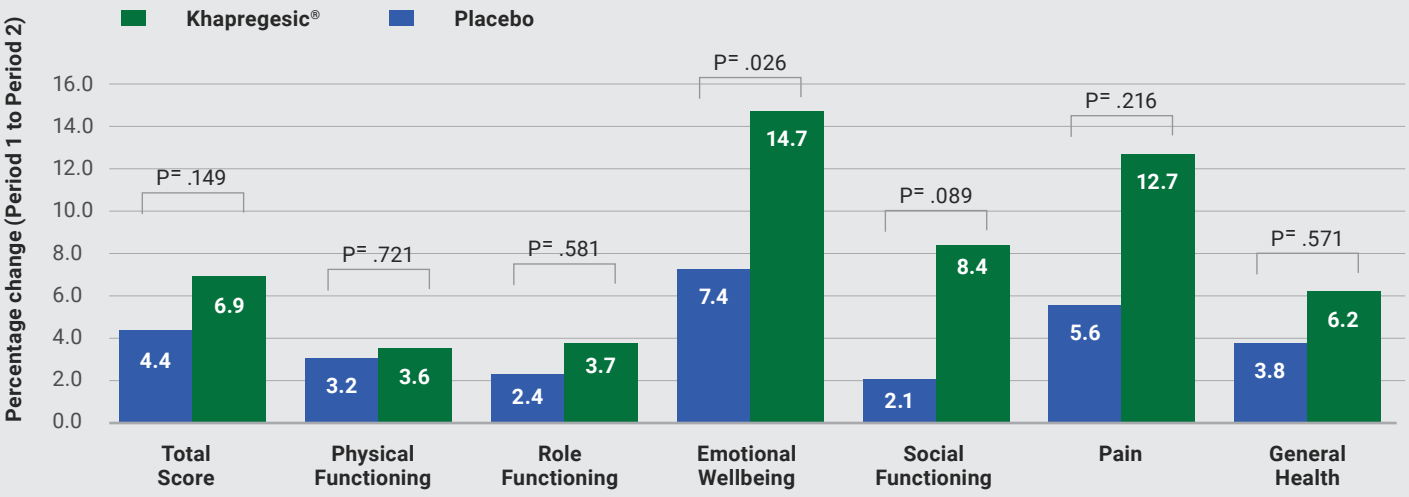

Figure 3: Percentage Change in SF-20 scores from Menstrual Period 1 to Menstrual Period 2 (FAS)

This Clinical Trial was independently conducted by Clinical Research Australia and funded by the company who developed Khapregesic®, Bioactive Natural Health Pty Ltd. This research and its important findings are scheduled for publication in the latter half of 2025.

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[1] Clinical Trial Sponsor: Bioactive Natural Health Pty Ltd trading as Hey Sister!, Head of Research: Rick Ferdinands, Co-founder and CEO.[2] Pain Reduction: Khapregesic® rating = 45.8 Placebo = 19.5. (45.8 - 19.3 = 26.3 / 19.3 X 100 = 136%) (see Pain Rating Figure 2.) [3] Pain drug usage: before Khapregesic® = 4.34 after using Khapregesic® = 2.29 (4.34 - 2.29 = 2.05 / 2.29 X 100 = 90%) (see Figure 4.) [4] Physical Score: Khapregesic® rating = 28.6 Placebo = 16.7. (28.6 - 16.7 = 11.9 / 16.7 X 100 = 71%) (see DSR Physical Score Figure 2.). [5] Psychological Score: Khapregesic® rating = 35.5 Placebo = 12.0. (35.5 - 12 = 23.5 / 12 X 100 = 196%) (see DSR Psychological Score Figure 2.) [6] Social Functioning: Khapregesic® rating = 8.4 Placebo = 2.1. (8.4 - 2.1 = 6.3 / 2.1 X 100 = 300%) (see Social Functioning Figure 3.)