Indications for Mutaflor® - Chronic Constipation

Probiotic Therapy of Chronic Constipation Mutaflor® vs. Placebo

MU 9202 - Study Overview

Design: randomised controlled trial with placebo
double blind
multi-centre

Duration: run-in phase: 1 week
treatment phase: 8 weeks
possible cross-over after 5 weeks

Objective: better than placebo

Criterion: weekly stool frequency

Patients: run-in phase: N = 134
treatment phase: N = 70 (35 per study arm)

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MU 9202 - Study Design

- **Run-in**
  - Placebo
  - Bisacodyl (Laxative)

- **Therapy**
  - Placebo
  - Cross-over, if ≤ 2 stools / week
  - Verum

- **Dose**
  - 1 x 4 capsules/d
  - 3x2 capsules/d
  - 1 x 4 capsules/d

- **Doctor / Patient Diary**
  - Week 0
  - Week 4
  - Week 8

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MU 9202 – Results: Efficacy (without cross-over patients)

stool frequency / week

- Placebo
- Verum
- Maximum
- Minimum

p < 0.001

N = 35 35 30 34 16 31

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MU 9202 – Results: Efficacy with cross-over patients

Stool frequency at week 4 ≤ 2 stools/week

Difference in (Δ week 4 to 8)

N = 13

N = 2