The probiotic drug for life!

Indications for Mutaflor®

Chronic Constipation

Clinical Efficacy and Safety of

_E. coli_ Strain Nissle 1917

(Mutaflor®)
Indications for Mutaflor® - Chronic Constipation

Probiotic Therapy of Chronic Constipation Mutaflor® vs. Lactulose

MU 8902 - Study Overview

Design: randomised
       open
       monocentric

Duration: run-in phase: 2 weeks
          treatment phase: 12 weeks

Objective: equivalence to Lactulose

Criterion: weekly stool frequency

Patients: run-in phase: N = 108
          treatment phase: N = 56 Mutaflor, 52 Lactulose

The probiotic drug for life!

MUTAFLOR®

Indications for Mutaflor® - Chronic Constipation
Probiotic Therapy of Chronic Constipation Mutaflor® vs. Lactulose

MU 8902 - Study Design

<table>
<thead>
<tr>
<th>Patients</th>
<th>Mutaflor®</th>
<th>Lactulose</th>
</tr>
</thead>
<tbody>
<tr>
<td>51</td>
<td>3 cps. / d</td>
<td>2 x 15 ml / d</td>
</tr>
<tr>
<td>46</td>
<td>not allowed</td>
<td>allowed</td>
</tr>
</tbody>
</table>

Visits

-2 (t₀) 0 (t₁) 4 (t₂) 8 (t₃) 12 (t₄) [weeks]

Patient diary


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Indications for Mutaflor® - Chronic Constipation

Probiotic Therapy of Chronic Constipation Mutaflor® vs. Lactulose

MU 8902 - Study Results

Stool frequency / week

<table>
<thead>
<tr>
<th>Weeks</th>
<th>Lactulose</th>
<th>Mutaflor</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>4.9 ± 2.8</td>
<td>5.2 ± 3.0</td>
</tr>
<tr>
<td>12</td>
<td>5.5 ± 2.0</td>
<td>6.3 ± 2.5</td>
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</tbody>
</table>

Normal stool consistency

<table>
<thead>
<tr>
<th>Weeks</th>
<th>Lactulose</th>
<th>Mutaflor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>43%</td>
<td>57%</td>
</tr>
<tr>
<td>12</td>
<td>70%</td>
<td>84%</td>
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</table>