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<thead>
<tr>
<th><strong>Name of company:</strong></th>
<th><strong>Tabulated Trial Report</strong></th>
<th><strong>Synopsis No.:</strong></th>
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<tr>
<td>Boehringer Ingelheim</td>
<td></td>
<td>n.a.</td>
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<tr>
<th><strong>Name of finished product:</strong></th>
<th><strong>EudraCT No.:</strong></th>
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<tr>
<td>Bisolvon®</td>
<td>C73 0634 2</td>
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<tr>
<th><strong>Name of active ingredient:</strong></th>
<th><strong>Page:</strong></th>
<th><strong>Volume:</strong></th>
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<tr>
<td>Bromhexine hydrochloride</td>
<td>1 of 2</td>
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<th><strong>Report date:</strong></th>
<th><strong>Trial No. / U No.:</strong></th>
<th><strong>Date of trial:</strong></th>
<th><strong>Date of revision (if applicable):</strong></th>
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<td>05 DEC 1972</td>
<td>U72-0088</td>
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**Title of trial:** Relazione sulla sperimentazione clinica del preparato Bisolvon supposte pediatriche.

**Principal/Coordinating Investigator:** Salomone, P.

**Trial sites:** Single center

**Publication (reference):** Boehringer Ingelheim in-house report, 05 December 1972

**Clinical phase:**

**Objectives:** Primary objective was to analyze safety profile of the Bisolvon® solution (particularly local and general tolerability) in paediatric patients. In addition, efficacy of Bisolvon® regarding improvement of bronchial symptoms was assessed (cough, expectoration, dyspnoea, fever)

**Methodology:** open, uncontrolled, single centre

**No. of subjects:** 15 children (8 male, 7 female), 1 month to 8 years old

**Diagnosis and main criteria for inclusion:** Paediatric patients with acute illness of the respiratory tract, acute cystic fibrosis attack (1 case)

**Test product:** Bisolvon® suppositories

**dose:** daily dose: 1–2 mg bromhexine/kg body weight

**mode of admin.:** rectal

**batch no.:** Z 7404

**Reference therapy:** none

**dose:**

**mode of admin.:**

**batch no.:**
## Summary – Conclusions

### Efficacy / Clinical Pharmacology Results:

In all cases the symptoms of dry cough changed to productive cough. Secretion improved, especially in the case of cystic fibrosis.

### Safety Results:

Overall tolerability was good, local tolerability was moderate in 5 cases. In one case treatment had to be interrupted due to diarrhoea. This adverse drug reaction has been observed in 4 further cases, too. It is not clear whether drug treatment caused these effects- in one case diarrhoea was clearly due to salmonellae.

### Conclusions:

Bisolvon® suppositories were generally well tolerated and are characterized by good and rapid therapeutic activity.