**Title of trial:** Pilot study in children with cystic fibrosis. The influence of an oral or parenteral administration of Bisolvon on antibiotic levels in blood and sputum.

**Principal/Coordinating Investigator:** Baran D.

**Trial sites:** Lung Disease Department, Paediatric Service, University Hospital St Pierre, Brussels, Belgium

**Publication (reference):** Boehringer Ingelheim in-house report.

**Clinical phase:** II

**Objectives:** Assessment of the efficacy of bromhexine in paediatric patients suffering from cystic fibrosis by its effect on antibiotic levels during antipseudomonal treatment in blood and sputum

**Methodology:** open-label, uncontrolled, single centre pilot study, comprising a control period: (3 aerosols of physiological saline), : Bisolvon i.v. and Bisolvon per os

Control period: 3 aerosols of physiological saline

Bisolvon per os: 3 x 4 mg/day

Bisolvon i.v. 8 mg/day

**No. of subjects:** 10 children

**Diagnosis and main criteria for inclusion:** children suffering from cystic fibrosis

acute exacerbation of pulmonary infection with *Ps. aeruginosa*
<table>
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<tr>
<th><strong>Name of company:</strong></th>
<th><strong>Tabulated Trial Report</strong></th>
<th><strong>Boehringer Ingelheim</strong></th>
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<tr>
<td><strong>Name of finished product:</strong></td>
<td>EudraCT No.:</td>
<td>n.a.</td>
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<tr>
<td>Bisolvon®</td>
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<td>Bromhexine hydrochloride</td>
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<td><strong>Module:</strong></td>
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<td><strong>Report date:</strong></td>
<td><strong>Trial No. / U No.:</strong></td>
<td><strong>Date of trial:</strong></td>
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**Test product:**
- Bisolvon per os 3 x 4 mg/day
- Bisolvon i.v. 3 x 1 amp (8 mg/day)

**Antibiotic dosages:**
- Azlocillin: 220 mg/kg given as 15 min i.v. infusion in 4 daily doses
- Tobramycin: 60 mg/m² of body surface every 6 hours as a continuous infusion

**dose:**
- 4 mg t.i.d. bromhexine

**mode of admin.:**
- Oral
- i.v.

**batch no.:**
- N/A

**Reference therapy:**
- none

**dose:**

**mode of admin.:**

**batch no.:**

**Duration of treatment:**
- 5 days

**Criteria for evaluation:**

**Efficacy / clinical pharmacology:**
- Effect of bromhexine treatment in paediatric patients suffering from cystic fibrosis by its effect on antibiotic levels during antipseudomonal treatment in blood and sputum

**Safety:**
- Tolerability
- Laboratory parameters
**Summary – Conclusions:**

**Efficacy / Clinical Pharmacology Results:**
No interactions with the antibiotic treatment could be observed.

**Safety Results:**
Treatment with bromhexine had no influence of the haematologic, hepatic and renal parameters in paediatric patients. Adverse events have not been reported.

**Conclusions:**
Results of study cannot be directly taken as a proof of efficacy, but underlines the lack of any interaction between Bisolvon® and the antibiotics administered to treat the pulmonary infections caused by *Pseudomonas aeruginosa*. 