

Trial sites: multicenter


Clinical phase: II

Objectives: Assessment of the efficacy of bromhexine in paediatric patients was assessed by its effect on asthmatic and bronchitic syndromes

Methodology: open, uncontrolled, multicentre (18 centers), clinical study

No. of subjects: 378  (273 m, 131 f, 10 of unknown sex) aged between 4 months and 16.5 years
4 months–1.5 yrs: 66
1.5–4 yrs: 110
4–10 yrs), 41 (range 10–16.5 yrs): 110

Diagnosis and main criteria for inclusion: asthmatic syndrome (182), spastic bronchitis (165), bronchitic syndrome (22), pneumonia (3), bronchiectasis (2) and spastic bronchitis in connection with infectious disease (4)

Test product: Bisolvon® suppositories (N125-AST; 8 mg Bromhexine/suppository) Contains also theophylline and papaverine
Name of company: Boehringer Ingelheim

Name of finished product: Bisolvon®

Name of active ingredient: Bromhexine hydrochloride, Theophylline, Papaverine

EudraCT No.: C72 0093 5

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Synopsis No.: n.a.

Name of company:

Boehringer Ingelheim

Tabulated Trial Report

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Volume:

n.a.

Report date:

21 DEC 1971

Trial No. / U No.:

U72-0069

Date of trial:

n.a.

Date of revision (if applicable):

n.a.

Dose:

Children 4 months to 1.5 years: 2–3 times 1 or 0.5 suppository daily (mainly 3 x 0.5).

1.5–4 years: 1–4 times 0.5 or 1–4 times 1 suppository daily (mostly 3 x 0.5 or 3 x 1).

4–10 years: 2–3 times 0.5, 2–3 times one, 2-3 times 2 or 4 times 1 suppository (mostly 3 x 1).

10–16 years: 2 times one or two, or 3 times 1 suppository daily (mainly 3 x).

Mode of admin.:

rectal

Batch no.:

N/A

Reference therapy:

none

Dose:

mode of admin.:

rectal

Batch no.:

N/A

Duration of treatment:

in average 7 days, ranging from 1 to 22 days.

Criteria for evaluation:

Efficacy / clinical pharmacology:

asthmatic syndrome, spastic bronchitis partly in connection with infectious diseases, pneumonia, bronchiectasis, honeycomb lung onset and duration of action

Safety:

Local tolerability

Laboratory parameters: haemogram, urinanalysis, liver enzymes (SGOT, SGPT)

Statistical methods:

Descriptive statistics
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### SUMMARY – CONCLUSIONS:

**Efficacy / clinical pharmacology results:**

Onset of action: 1.6 hours (n=232 patients)

The efficacy was rated as good or very good in 75.1 %, as satisfactory in 10.8 % and as not satisfactory in 8.5 % of the evaluable patients. According values for asthmatic syndrome were 75.8 %, for spastic bronchitis 75.2 % and for bronchitic syndrome 68.2 %. Bisolvon® suppositories were most effective for the indications asthmatic syndrome, spastic bronchitis and bronchitic syndrome.

**Safety results:**

In 4 cases fatigue was indicated as side effect. Local tolerability was judged as very good in 338 children. Laboratory values assessed in 136 children were all within the normal range. There was no influence of the haematologic, hepatic and renal parameters.

**Conclusions:**

Best results were obtained for asthmatic and bronchitic syndromes (very good therapeutic efficacy in 75 % of patients). Therefore suppositories may be considered an effective application form for treatment of asthmatic-bronchitic syndrome in children. Treatment with bromhexine had no influence of the haematologic, hepatic and renal parameters in paediatric patients.