Title of trial: Open study with IK19 in 50 children and 50 adults.

Principal/Coordinating Investigator: Goiz Duran I, Landa Palos J, Sanchez Martinez J

Trial sites: Single center

Publication (reference):

Clinical phase: II

Objectives: To assess analgetic and spasmolytic effect as well as tolerability and possible adverse events of IK-19 (Hyoscin-N-butylbromide 10 mg + paracetamol 500 mg), administered as film coated tablet.

Methodology: Open, uncontrolled, prospective study

No. of subjects: 50 school children (23 m; 27 f) aged 10 years on average (range 5 – 16 years)

Diagnosis and main criteria for inclusion: Intestinal spasm (e.g. gastroenteritis, enterocolitis, dyskinesia of bile ducts, cholecystitis, dysmenorrhoea with spasm)

Test product: Hyoscine-N-butylbromide 10 mg + Paracetamol 500 mg (film-coated tablet)

dose: 1 film-coated tablet thrice daily

mode of admin.: oral

batch no.: IK-19

Reference therapy: none

dose: 

mode of admin.: 

batch no.: 

Proprietary confidential information
© 2011 Boehringer Ingelheim International GmbH or one or more of its affiliated companies. All rights reserved. This document may not - in full or in part - be passed on, reproduced, published or otherwise used without prior written permission.
**Name of company:**
Boehringer Ingelheim

**Name of finished product:**
Buscopan® Plus

**EudraCT No.:**
n.a.

**Name of active ingredient:**
Butyl-N-scopolamine bromide
Paracetamol

**Module:**
n.a.

**Page:**
n.a.

**Synopsis No.:**
n.a.

**Report date:**
01-Jan-1979

**Trial No. / U No.:**
n.a. / U79-0384

**Volume:**
n.a.

**Date of trial:**
n.a.

**Date of revision:**
n.a.

---

**Duration of treatment:**
3 to 10 days

**Criteria for evaluation:**

- **Efficacy / clinical pharmacology:**
Pain intensity of school children
Therapeutic efficacy was assessed taken clinical symptoms as basis

- **Safety:**
Adverse events, tolerability

**Statistical methods:**
Descriptive statistics

---

**SUMMARY – CONCLUSIONS:**

**Efficacy / clinical pharmacology results:**
After treatment pain intensity has been rated as following: strong: 3 %, moderate 8 %, low 3 % and disappeared 81 %
The results of this study show that the drug combination of hyoscine N-butylbromide 10 mg and paracetamol 500 improved spastic pain in the majority of patients suggesting that test product exerts good analgesic and antispasmodic effects. Onset of action was observed within 30-60 minutes after oral administration. The effect lasted several hours. Therefore administration every 8 hours is considered a convenient interval.

**Safety results:**
In addition, it should be noted that no unwanted side effects like dry mouth, mydriasis, etc., occurred. The drug was well tolerated by both adults and school children are doing well.

**Conclusions:**
Drug combination of hyoscine N-butylbromide 10 mg and paracetamol 500 mg (IK -19) has shown good therapeutic efficacy and good tolerability.