Clinical Study Synopsis for Public Disclosure

This clinical study synopsis is provided in line with **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

The synopsis - which is part of the clinical study report - had been prepared in accordance with best practice and applicable legal and regulatory requirements at the time of study completion.

The synopsis may include approved and non-approved uses, doses, formulations, treatment regimens and/or age groups; it has not necessarily been submitted to regulatory authorities.

A synopsis is not intended to provide a comprehensive analysis of all data currently available regarding a particular drug. More current information regarding a drug is available in the approved labeling information which may vary from country to country.

Additional information on this study and the drug concerned may be provided upon request based on **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

2. SYNOPSIS

Name of company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Not applicable				
Name of active ingredient: Epinastine Nasal		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:** to		**Addendum No.:**
Report date: 09 April 2002	**Number:** 262.261	**Study period (years):** 08/2001 – 09/2001		

Title of study:	A double-blind, randomised, placebo-controlled single increasing dose tolerance study in healthy male volunteers after intranasal application of Epinastine Nasal (dosage: 0.035 mg (0.025 % solution) – 0.42 mg (0.3 % solution))
Investigator:	[redacted]
Study centre:	Human Pharmacology Centre Ingelheim, Boehringer Ingelheim Pharma KG, Ingelheim, Germany
Publication (reference):	Not applicable
Clinical phase:	I
Objectives:	Safety, tolerability and pharmacokinetics
Methodology:	Randomised, single rising doses, double-blind, parallel groups, placebo-controlled
No. of subjects entered:	
total:	39
each treatment:	Placebo – 10; Epinastine Nasal: 0.035 mg (0.025 %) - 6; 0.07 mg (0.05 %) - 5; 0.14 mg (0.1 %) - 6; 0.28 mg (0.2 %) - 6; 0.42 mg (0.3 %) – 6
Diagnosis and main criteria for inclusion:	Healthy male volunteers, age 21 – 50 years, Broca-Index: ± 20 %
Test product:	Epinastine Nasal
dose:	0.035 mg (0.025 %), 0.07 mg (0.05 %), 0.14 mg (0.1 %), 0.28 mg (0.2 %) and 0.42 mg (0.3 %) (doses refer to the amount of the active ingredient of the drug, i.e. free base)
mode of admin.:	Intranasal application
Duration of treatment:	One day at each dose level
Reference therapy:	Placebo
dose:	Matching Epinastine Nasal solution
mode of admin.:	Intranasal application

Name of company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
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Criteria for evaluation:

Efficacy: Not applicable

Safety: Blood pressure, pulse rate, ECG, laboratory parameters, adverse events, pharmacokinetics C_{max}, $AUC_{0-\infty}$, AUC_{0-tz}, t_{max}, $t_{½}$, Ae, individual time courses of drug plasma concentration

Statistical methods: Descriptive analysis, ANOVA

SUMMARY - CONCLUSIONS:

Efficacy results: Pharmacokinetics

No pharmacokinetic measurements were performed due to the stop of the Epinastine Nasal project for internal reasons. Therefore, only the clinical past of this study is reported here.

Safety results: Two subjects reported three adverse events of mild to moderate intensity (sore throat, headache: not drug related; bitter taste at highest dose: drug related).

Conclusions: Epinastine Nasal in the dose and concentration range described in this report was safe and well tolerated. The local tolerability was good.

There was no evidence of a dose dependent increase in frequency or intensity of adverse events. The clinical findings of this single dose study confirm that the compound can be safely administered to humans without producing adverse events or clinical findings which could raise objections to further clinical trials.