

Synopsis of study report: 46/96
Location in Module 5:

Study Code:
BY217/FHP001

Report Date:
06-Sep-1996

Title of the study:

Safety and tolerability of the new phosphodiesterase inhibitor B9302-107 administered to healthy male volunteers as ascending single oral doses

Study center(s):

Dept. of Clinical Pharmacology, Byk Gulden, 78467 Konstanz, Germany

Publication (reference):

Not available

Studied period (years):

December 1995 - January 1996

Clinical phase:

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Objectives:

- To assess safety and tolerability

Methodology:

Single-blind, placebo-controlled, 4-period change-over with increasing single doses and interspersed placebo administration

No. of subjects (total and for each treatment):

4 male volunteers, aged 21 – 30 (median = 28) years

Diagnosis and criteria for inclusion:

Healthy male volunteers

Duration of treatment:

Single oral dose

Test product:

Roflumilast (BY217, tablets à 0.25 mg)

Roflumilast (BY217 tablets à 2.5 mg)

Dose:

1.0 mg, 2.5 mg and 5.0 mg B9302-107

Mode of administration:

p.o.

Batch No.:

063495/1 (tablet with 0.25 mg)

062496/1 (tablet with 2.5 mg)

Reference product:

Placebo tablets

Dose:

0.0 mg

Mode of administration:

Oral

Batch No.:

064495/1

Criteria for evaluation:

Tolerability: questionnaire of subjective well-being, adverse events

Safety: vital signs, ECG, clinical laboratory, olfactory test

Highest dose only: serum levels of B9302-107

Statistical methods:

Descriptive analysis

SUMMARY - CONCLUSIONS**Summary:**Results:

Headache occurred in $\frac{1}{4}$ volunteers at the 1 mg dose. After intake of 2.5 mg B9302-107 $\frac{1}{3}$ volunteers complained of mild headache, dizziness, transpiration and salivation, abdominal pain, palpitations and diarrhea, $\frac{1}{3}$ complained of severe headache and disturbed sleep and $\frac{1}{3}$ complained of mild palpitations and diarrhea, moderate nausea and dizziness. Vital signs, ECG, olfactory test and clinical laboratory did not show clinical relevant alterations. Serum level in $\frac{1}{3}$ showed a C_{\max} of 11.04 $\mu\text{g/l}$ ($t_{\max} = 0.5 \text{ h}$) and a $t_{1/2}$ of 14.3 hours after intake of 2.5 mg.

Conclusion:

B9302-107 was safe and well tolerated up to and including 1 mg in 4/4 volunteers following single oral intake.