

A. INGREDIENT NAME:

PHENYLTOLOXAMINE DIHYDROGEN CITRATE

B. Chemical Name:

N, N-Dimethyl-2-(Alpha-Phenyl-O-Toloxyl)Ethylamine, Dihydrogen Citrate
2-(2-Benzylphenoxy)-NN-dimethyl-ethylamine dihydrogen citrate

C. Common Name:

Rinurel, Pholtex, Aust.-Codipront; Fr.- Biocidan: There are various names from different countries. See file.

D. Chemical grade or description of the strength, quality, and purity of the ingredient:

Assay: 99.9%

E. Information about how the ingredient is supplied:

White crystalline powder, odorless, tasteless, crystals from water or methanol

F. Information about recognition of the substance in foreign pharmacopeias:

G. Bibliography of available safety and efficacy data including peer reviewed medical literature:

Sunshine, A., Zigelboim, I., and De Castro, A. Augmentation of acetaminophen analgesia by the antihistamine phenyltoloxamine. *J Clin Pharmacol*; 1989; 29(7): 660-664.

Falliers, C. J., Redding, M. A., and Katsampes, C.P. Inhibition of cutaneous and mucosa allergy with phenyltoloxamine. *Ann Allergy*, 1978; 41(3): 140-144.

1998-3454-02-35-BDL22

H. Information about dosage forms used:

Expectorant
Suspension
Tablet

I. Information about strength:

25-50mg - 3-4 times daily

J. Information about route of administration:

Orally

K. Stability data:

Melts at about 138-140° centigrade
Stable

L. Formulations:

M. Miscellaneous Information:

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TITLE: Augmentation of acetaminophen analgesia by the antihistamine phenyltoloxamine.

AUTHOR: Sunshine A; Zigelboim I; De Castro A; Sorrentino JV; Smith DS; Bartizek RD; Olson NZ

AUTHOR AFFILIATION: New York University Medical Center, New York.

SOURCE: J Clin Pharmacol 1989 Jul;29(7):660-4

NLM CIT. ID: 89341003

ABSTRACT: A double-blind, placebo-controlled, parallel-group study was performed to compare the analgesic activity of the combination of 650 mg acetaminophen plus 60 mg phenyltoloxamine citrate with that of 650 mg acetaminophen alone. Two hundred female inpatients who had severe pain associated with a recent episiotomy procedure were randomly assigned to receive a single dose of one of the two active treatments or a placebo. Analgesia was assessed over a 6-hour period. Treatments were compared on the basis of standard subjective scales for pain intensity and relief, a number of derived variables based on these data and two global measures. For essentially all measures, the two active treatments were significantly superior to the placebo control. The combination was significantly superior to acetaminophen alone for all analgesic measures including SPID, TOTAL, and global ratings. The results of this study demonstrate that 60 mg phenyltoloxamine produces significant augmentation of the analgesic activity of 650 mg acetaminophen in postepisiotomy pain.

MAIN MESH SUBJECTS: Acetaminophen/ADMINISTRATION & DOSAGE/*THERAPEUTIC USE
Benzhydryl Compounds/ADMINISTRATION & DOSAGE/*THERAPEUTIC USE
Histamine H1 Antagonists/*THERAPEUTIC USE
Pain, Postoperative/*DRUG THERAPY

ADDITIONAL MESH SUBJECTS: Adolescence
Adult
Comparative Study
Double-Blind Method
Drug Synergism
Drug Therapy, Combination
Female
Human
Pregnancy
Random Allocation
Support, Non-U.S. Gov't
Time Factors

PUBLICATION TYPES: CLINICAL TRIAL
JOURNAL ARTICLE
RANDOMIZED CONTROLLED TRIAL

LANGUAGE: Eng

REGISTRY NUMBERS: 0 (Benzhydryl Compounds)
0 (Histamine H1 Antagonists)
103-90-2 (Acetaminophen)
92-12-6 (phenyltoloxamine)

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TITLE: Inhibition of cutaneous and mucosal allergy with phenyltoloxamine.

AUTHOR: Falliers CJ; Redding MA; Katsampes CP

SOURCE: Ann Allergy 1978 Sep;41(3):140-4

NLM CIT. ID: 78255039

ABSTRACT: A dose-and-time related-effect of oral phenyltoloxamine citrate, a Class I, H1 antihistamine compound, has been demonstrated against allergen-induced wheal-and-erythema skin reactions among 10 adults with a diagnosis of allergic rhinitis and seasonal pollinosis. Clinical improvement in the existing symptoms of rhinorrhea, nasal obstruction, pruritus and sneezing, showed a significant correlation with the inhibition of reagin-mediated skin reactivity caused by phenyltoloxamine. No adverse side effects were observed. It can be concluded that oral phenyltoloxamine citrate possesses antihistaminic properties and a range of safety which make it a useful agent for the symptomatic management of upper respiratory allergy.

MAIN MESH SUBJECTS: Ethanolamines/*THERAPEUTIC USE

SUBJECTS: Hay Fever/*PREVENTION & CONTROL

ADDITIONAL MESH SUBJECTS: Adolescence
Adult
Dose-Response Relationship, Drug
Histamine H1 Antagonists/THERAPEUTIC USE
Human
Male
Mucous Membrane/IMMUNOLOGY
Skin Tests

PUBLICATION TYPES: JOURNAL ARTICLE

LANGUAGE: Eng

PHENYLTOLOXAMINE DIHYDROGEN CITRATE

Rodent LD50 is approx. 1.5 g/kg.

Toxicology has not been thoroughly investigated.
Has caused nausea, vomiting, sedation and dizziness.

Used as an antihistamine.

REFERENCES

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