

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

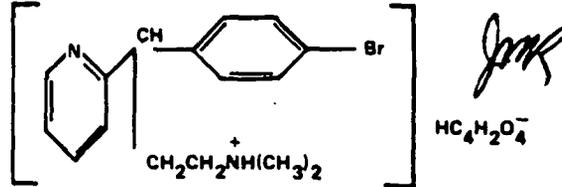
APPLICATION NUMBER:

85888

DRAFT FINAL PRINTED LABELING

BROMPHENIRAMINE MALEATE TABLETS

DESCRIPTION: Brompheniramine Maleate is an antihistaminic agent with the chemical structure:



It is a white, odorless, crystalline powder, the solution of which has a pH between 4 and 5.

ACTIONS: Brompheniramine Maleate is an antihistaminic drug which possesses anticholinergic and sedative effects.

INDICATIONS: Brompheniramine Maleate is indicated for the following conditions:

1. Perennial and seasonal allergic rhinitis.
2. Vasomotor rhinitis.
3. Allergic conjunctivitis due to inhalant allergens and foods.
4. Mild, uncomplicated allergic skin manifestations of urticaria and angioedema.
5. Amelioration and prevention of allergic reactions to blood or plasma in patients with a known history of such reactions.
6. Dermographism.
7. As therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.

CONTRAINDICATIONS: This drug should not be used in newborn or premature infants. Antihistamine should NOT be used to treat lower respiratory symptoms. Do not use this drug in patients with: Hypersensitivity to the preparation
Asthmatic attack
Narrow-angle glaucoma
Prostatic hypertrophy
Stenosing peptic ulcer
Pyloroduodenal obstruction
Bladder neck obstruction
Patients receiving monamine oxidase inhibitors

WARNINGS: This drug may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a vehicle or operating machinery. This drug may impair mental alertness in children. The concomitant use of alcohol or other central nervous system depressants may have an additive effect. Patients should be warned accordingly.

USAGE IN PREGNANCY: Although there is no evidence that the use of this drug is detrimental to the mother or fetus, the use of any drug in pregnancy should be carefully deliberated. This product may cause an inhibition of lactation.

USAGE IN CHILDREN: In infants and children particularly, antihistamines in overdose may produce convulsions and/or death.

PRECAUTIONS: Brompheniramine Maleate has an atropine-like action and should be used with caution in patients who have increased intraocular pressure, hyperthyroidism, cardiovascular disease, hypertension or in patients with a history of bronchial asthma.

ADVERSE REACTIONS: The following adverse reactions have been reported:

Drowsiness	Confusion
Nervousness	Restlessness
Nausea	Vomiting
Diarrhea	Blurring of Vision
Diplopia	Headache
Insomnia	Urticaria
Epigastric Distress	Nasal Stuffiness
Difficulty in urination	Constipation
Tightness of the chest and wheezing	
Thickening of bronchial secretions	
Dryness of mouth, nose and throat	
Tingling, heaviness and weakness of hands	
Vertigo	Palpitation
Drug rash	Hemolytic anemia
Hypotension	Anaphylaxis

DOSAGE AND ADMINISTRATION: Oral dose - Adults: The usual adult dose is 4 mg. three or four times daily. Children: For children over 20 pounds the usual dose is 2 mg. three or four times daily.

HOW SUPPLIED: Brompheniramine Maleate, 4 mg. package in bottles of 100 and 1000.

CAUTION: Federal Law prohibits dispensing without prescription.

DATE OF ISSUE: October 1977

Manufactured by:
CHROMALLOY PHARMACEUTICALS, INC.

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APR 30 1978

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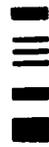
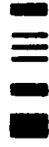
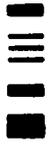
DATE OF ISSUE: October 1977

Manufactured by:
CHROMALLOY PHARMACEUTICALS, INC.
LOS ANGELES, CA 90066

ORIGINAL

45 888

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4/25/78



USUAL DOSE:
See package insert for full information.

NDC-0413-0825-10

BROMPHENIRAMINE MALEATE TABLETS NF

4 mg.

CAUTION: Federal Law Prohibits Dispensing Without Prescription

1000 TABLETS

APPROVED APR 22 1978



NDC-0413-0825-10

BROMPHENIRAMINE MALEATE TABLETS NF

4 mg.

CAUTION: Federal Law Prohibits Dispensing Without Prescription

1000 TABLETS

APPROVED APR 22 1978



NDC-0413-0825-10

BROMPHENIRAMINE MALEATE TABLETS NF

4 mg.

CAUTION: Federal Law Prohibits Dispensing Without Prescription

1000 TABLETS

APPROVED APR 26 1978



NDC-0413-0825-10

BROMPHENIRAMINE MALEATE TABLETS NF

4 mg.

CAUTION: Federal Law Prohibits Dispensing Without Prescription

1000 TABLETS

APPROVED APR 26 1978



Each tablet contains:
Brompheniramine Maleate 4 mg.
Lot No.:
Exp. Date:

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Lot No.:
Exp. Date:

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Lot No.:
Exp. Date:

Each tablet contains:
Brompheniramine Maleate 4 mg.
Lot No.:
Exp. Date:

NDC-4413-0022-01 APR 26 1978
Each tablet contains:
Brompheniramine
Maleate 4 mg.
Lot No.:
Exp. Date:
**BROMPHENIRAMINE
MALEATE
TABLETS NF
4 mg.**
CAUTION: Federal Law Prohibits
Dispensing Without Prescription.
100 TABLETS
USUAL DOSE:
See package insert for
full information.



APPROVED NDC-4413-0022-01 APR 26 1978
Each tablet contains:
Brompheniramine
Maleate 4 mg.
Lot No.:
Exp. Date:
**BROMPHENIRAMINE
MALEATE
TABLETS NF
4 mg.**
CAUTION: Federal Law Prohibits
Dispensing Without Prescription.
100 TABLETS
USUAL DOSE:
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Lot No.:
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100 TABLETS
USUAL DOSE:
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Pharmacy:
M.D. No. 85-888 Rec'd 10/16/77
[Signature]
9-25-78

ORIGINAL