BROVEX PEB- brompheniramine maleate and phenylephrine hydrochloride liquid
MCR American Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

BrōveX™PEB
LIQUID

Drug Facts

Active ingredients (in each 5 mL teaspoonful)	***Purpose***
Brompheniramine Maleate 4 mg	Antihistamine
Phenylephrine HCl 10 mg	Decongestant

Uses

temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages

Warnings

Do not exceed recommended dosage.

Do not use this product

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- heart disease
- high blood pressure
- thyroid disease
- diabetes mellitus
- difficulty in urination due to enlargement of the prostate gland

Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.

When using this product

- excitability may occur, especially in children
- may cause drowsiness

- sedatives and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- nervousness, dizziness, or sleeplessness occur
- If symptoms do not improve within 7 days or are accompanied by fever, consult a doctor
- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental overdose, seek professional help or contact a Poison Control Center immediately. 1-800-222-1222

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:	1 teaspoonful (5 mL) every 4 hours, not to exceed 6 teaspoonfuls in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age:	1/2 teaspoonful (2.5 mL) every 4 hours, not to exceed 3 teaspoonfuls in 24 hours, or as directed by a doctor
Children under 6 years of age:	Consult a doctor

Other information

Store at 20°-25°C (68°-77°F); excursions permitted to 15°- 30°C (59°-86°F) [see USP Controlled Room Temperature].

Inactive ingredients

Bubblegum Flavor, Citric Acid, Methyl Paraben, Potassium Citrate, Potassium Sorbate, Propyl Paraben, Propylene Glycol, Purified Water, Sorbitol Solution 70%, Sucralose

Question? Comments?

Call 1-800-793-2145

Rev. 03/11

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC 58605-152-01

BrōveX™PEB
LIQUID

Antihistamine • Decongestant

Sugar Free • Alcohol Free • Dye Free • Gluten Free

Each teaspoonful (5 mL) for oral administration

contains:	
Brompheniramine Maleate	**4 mg**
Phenylephrine HCl	**10 mg**

Bubblegum Flavor

This bottle is not to be dispensed to consumer.

Tamper evident by foil seal under cap. Do not use if foil seal is broken or missing.

Dispense in a tight container with a child-resistant cap.

Manufactured for:
PERNIX
THERAPEUTICS
Gonzales, LA 70737

16 fl oz (473 mL)

BROVEX PEB

brompheniramine maleate and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58605-152
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Brompheniramine Maleate (UNII: IXA7C9ZN03) (Brompheniramine - UNII:H57G17P2FN)	Brompheniramine Maleate	4 mg in 5 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Methylparaben (UNII: A2I8C7HI9T)	
Potassium Citrate (UNII: EE90ONI6FF)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	
Propylparaben (UNII: Z8IX2SC1OH)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Sorbitol (UNII: 506T60A25R)	
Sucralose (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BUBBLE GUM	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58605-152-01	473 mL in 1 BOTTLE, PLASTIC		
2	NDC:58605-152-02	20 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	11/30/2007	

Labeler - MCR American Pharmaceuticals, Inc. (783383011)

Establishment

Name	Address	ID/FEI	Business Operations
MCR American Pharmaceuticals, Inc.		783383011	MANUFACTURE

Revised: 4/2011 MCR American Pharmaceuticals, Inc.