DEXBROMPHENIRAMINE MALEATE AND PHENYLEPHRINE HYDROCHLORIDE- dexbrompheniramine maleate and phenylephrine hydrochloride tablet
Westminster Pharmaceuticals, LLC

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.

Dexbrompheniramine Maleate and Phenylephrine HCl

DRUG FACTS

Active ingredients (in each tablet)	***Purpose***
Dexbrompheniramine Maleate 2 mg	Antihistamine
Phenylephrine HCL 10 mg	Nasal Decongestant

Uses

Temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other upper 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
- trouble urinating due to enlargment of the prostate gland
- heart disease
- high blood pressure
- thyroid disease
- diabetes

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.

When using this product

- excitability may occur, especially in children
- may cause drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or are accompanied by fever

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

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Do not exceed recommended dosage.

Adults and children 12 years of age and over:	1 tablet every 4 to 6 hours, not to exceed 6 tablets in 24 hours or as directed by doctor.
Children 6 to under 12 years of age:	1/2 tablet every 4 to 6 hours, not to exceed 3 tablets in 24 hours or as directed by doctor.
Children under 6 years of age:	Consult a doctor.

Other Information

Store at 15º-30ºC (59º-86ºF). Supplied in a tight, light resistant container with a child-resistant cap. Dexbrompheniramine Maleate and Phenylephrine HCl tablets are purple, oval shaped, scored tablets, debossed "WP" bisect "197" on one side and plain on the other.

Inactive ingredients

Croscarmellose sodium, D&C Red #27 aluminum lake, FD&C Blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, pregelatinized starch, silicon dioxide.

Questions? Comments?

Call 1-844-221-7294

PRINCIPAL DISPLAY PANEL - 60 Tablet Bottle Label

NDC 69367-197-60

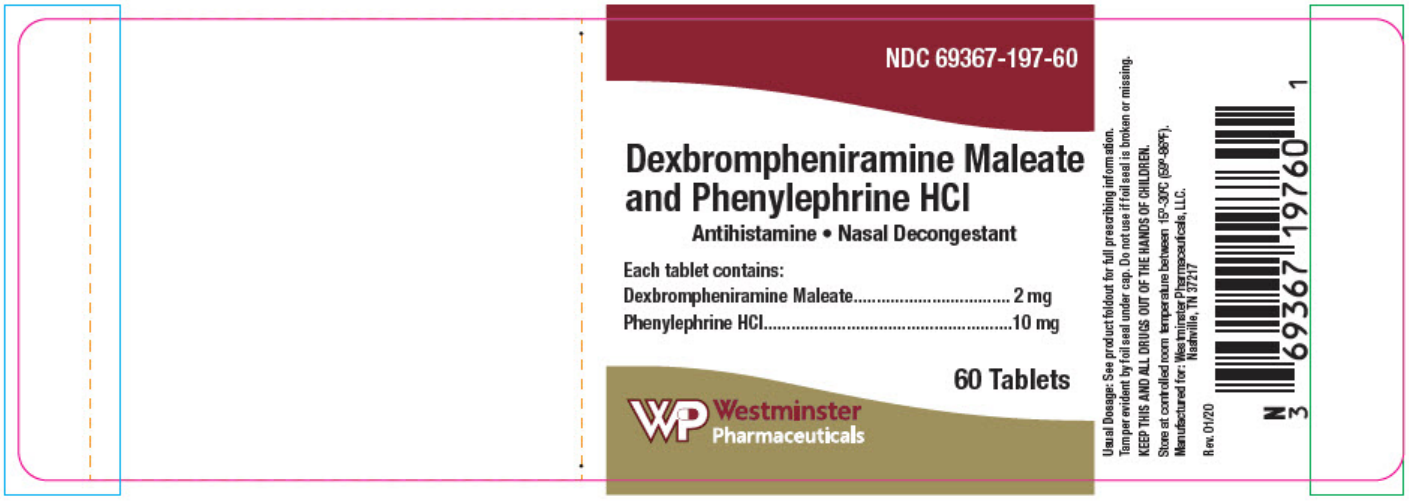
Dexbrompheniramine Maleate
and Phenylephrine HCl

Antihistamine • Nasal Decongestant

Each tablet contains:
Dexbrompheniramine Maleate
2 mg
Phenylephrine HCl
10 mg

60 Tablets

Westminster
Pharmaceuticals



DRUG FACTS (continued)

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Manufactured for:
Westminster Pharmaceuticals, LLC.
Nashville, TN 37217 Rev. 01/20

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DEXBROMPHENIRAMINE MALEATE AND PHENYLEPHRINE HYDROCHLORIDE

dexbrompheniramine maleate and phenylephrine hydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69367-197
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXBROMPHENIRAMINE MALEATE (UNII: BPA9UT29BS) (DEXBROMPHENIRAMINE - UNII:75T64B71RP)	DEXBROMPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	PURPLE	**Score**	2 pieces
Shape	OVAL	**Size**	11mm
Flavor		**Imprint Code**	WP;197
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-197-60	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/25/2018	06/03/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	10/25/2018	06/03/2024

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 10/2018 Westminster Pharmaceuticals, LLC