

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

*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.*

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**Dexbrompheniramine Maleate and Phenylephrine HCl**

**DRUG FACTS**

<b><i>Active ingredients (in each tablet)</i></b>	<b><i>Purpose</i></b>
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 enlargement 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 15°-30°C (59°-86°F). 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**

colloidal silicon dioxide, croscarmellose sodium, D&C Red #27, dibasic calcium phosphate dihydrate, FD&C Blue #1, magnesium stearate, and microcrystalline cellulose.

#### **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

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

**WP** Westminster  
Pharmaceuticals

Usual Dosage: See product foldout for full prescribing information.  
Tamper evident hybrid seal under cap. Do not use if foil seal is broken or missing.  
**KEEP THIS AND ALL DRUGS OUT OF THE HANDS OF CHILDREN.**  
Store at controlled room temperature between 15°-30°C (59°-86°F).  
Manufactured for: Westminster Pharmaceuticals, LLC.  
Olive Branch, MS 38654  
Rev. 10/18

  
3 69367 19760 1

<b>DRUG FACTS</b> (continued)	
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<b>Manufactured for:</b> Westminster Pharmaceuticals, LLC. Olive Branch, MS 38654 Rev. 10/18	
<b>DRUG FACTS</b>	
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Dexbrompheniramine	
Maleate 2 mg.....	Antihistamine
Phenylephrine	
HCL 10 mg.....	Nasal Decongestant
<b>Uses</b> 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	
<b>Warnings</b> Do not exceed recommended dosage. Do not use this product ■ if you are now taking a prescription	
Lift Here	

<b>DRUG FACTS</b> (continued)	
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.	
<b>Ask a doctor before use if you have</b> ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to enlargement of the prostate gland ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes	
<b>Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.</b> <b>When using this product</b> ■ 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	
<b>Stop use and ask a doctor if</b> ■ nervousness, dizziness, or sleeplessness occur ■ symptoms do not improve within 7 days or are accompanied by fever	
<b>If pregnant or breast-feeding, ask a health professional before use.</b>	
<b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.	
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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)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

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	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	10/25/2018	

**Labeler** - Westminster Pharmaceuticals (079516651)