DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE- doxylamine succinate 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.

Doxylamine Succinate and Phenylephrine HCl

DRUG FACTS

Active ingredients (in each tablet)	***Purpose***
Doxylamine Succinate 7.5mg	Antihistamine
Phenylephrine HCl 10mg	Nasal Decongestant

Uses

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

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

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

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

tranquilizers.

When using this product

- exctability may occur, especially in children
- may cause marked 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 hours, not to exceed 6 tablets in 24 hours.
Children 6 to 12 years of age:	1/2 tablet every 4 hours, not to exceed 3 tablets in 24 hours.
Children 6 years of age and under:	Consult a physician.

Other Information

Store at 15°-30°C (59°-86°F)

Supplied in a tight, light-resistant container with a child-resistant cap. Doxylamine Succinate and Phenylephrine HCl tablets are light blue, caplet shaped, scored tablets, debossed "WP" bisect "199" on one side and plain on the other.

Inactive ingredients

FD&C Blue #2, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide, Sodium Starch Glycolate

Questions? Comments?

Call 1-844-221-7294

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

NDC 69367-199-01

Doxylamine Succinate
and Phenylephrine HCl

Antihistamine • Nasal Decongestant

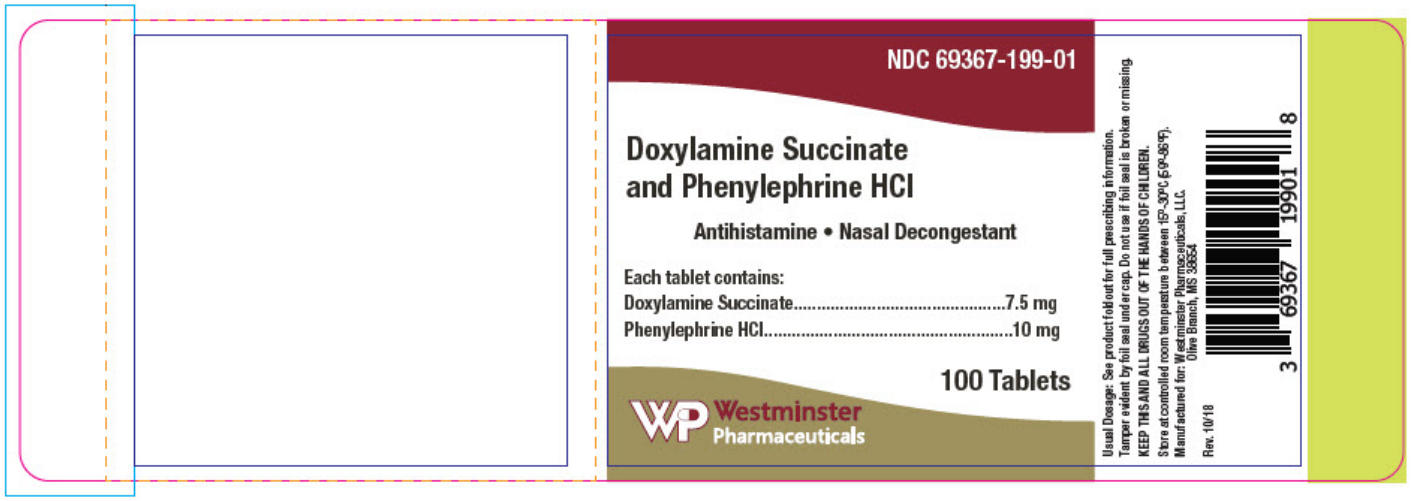
Each tablet contains:

Doxylamine Succinate
7.5 mg

Phenylephrine HCl
10 mg

100 Tablets

Westminster
Pharmaceuticals



DRUG FACTS (continued)

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Manufactured for:
Westminster Pharmaceuticals, LLC.
Olive Branch, MS 38654 Rev. 10/18

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DOXYLAMINE SUCCINATE AND PHENYLEPHRINE HYDROCHLORIDE
doxylamine succinate and phenylephrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69367-199
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	7.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	BLUE	**Score**	2 pieces
Shape	OVAL	**Size**	14mm
Flavor		**Imprint Code**	WP;199
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-199-01	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/25/2018	05/01/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	10/25/2018	05/01/2024

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 10/2018 Westminster Pharmaceuticals, LLC