

PYRILAMINE MALEATE AND DEXTROMETHORPHAN HYDROBROMIDE-
pyrilamine maleate and dextromethorphan hydrobromide liquid
Westminster Pharmaceuticals, LLC

Pyrilamine Maleate and Dextromethorphan Hydrobromide

Drug Facts

<i>Active ingredient (in each 5 mL teaspoonful)</i>	<i>Purpose</i>
Dextromethorphan HBr 7.5 mg	Antitussive
Pyrilamine Maleate 7.5 mg	Antihistamine

Uses

temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation associated with a cold
- alleviates cough to help you sleep
- nonnarcotic cough suppressant for the relief of cough

Warnings

Do not exceed recommended dosage.

- a persistent cough may be a sign of a serious condition. If cough persist for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache, consult a doctor.

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
- for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

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

When using this product

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

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.

Directions**Do not exceed recommended dosage.**

Adults and children 12 years of age and over:	4 teaspoonfuls every 6-8 hours, not to exceed 16 teaspoonfuls in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age:	2 teaspoonfuls every 6-8 hours, not to exceed 8 teaspoonfuls in 24 hours, or as directed by a doctor
Children under 6 years of age:	Consult a doctor

Other information

Store at room temperature 15°C-30°C (59°F-86°F)

Inactive ingredients

Anhydrous citric acid, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose.

Questions or Comments?

Call 1-844-221-7294 M-F (9 a.m. to 5 p.m. EST)

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC: 69367-398-16

Pyrilamine Maleate
and
Dextromethorphan HBr
Liquid

Antitussive • Antihistamine

Sugar Free • Alcohol Free

• Dye Free • Gluten Free

Each teaspoonful (5 mL) for oral administration contains:

Dextromethorphan HBr

7.5 mg

Pyrilamine Maleate

7.5 mg

Candy Apple Flavor

Tamper evident by foil seal under cap.

Do not use if foil is broken or missing.

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

16oz. (473mL)

Westminster

Pharmaceuticals

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<h2>Pyrilamine Maleate and Dextromethorphan HBr Liquid</h2>	
Antitussive • Antihistamine Sugar Free • Alcohol Free • Dye Free • Gluten Free	
Each teaspoonful (5 mL) for oral administration contains: Dextromethorphan HBr.....7.5 mg Pyrilamine Maleate.....7.5 mg	
Candy Apple Flavor	
Tamper evident by foil seal under cap. Do not use if foil is broken or missing.	
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Warnings Do not exceed recommended dosage. ■ a persistent cough may be a sign of a serious condition. If cough persist for more than 1 week, tends to recur, or is accompanied by a fever, rash, or persistent headache, consult a doctor. 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 ■ for persistent or chronic cough such as occurs with smoking asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a doctor	
Ask a doctor before use if you have ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ difficulty in urination due to enlargement of the prostate gland	
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When using this product ■ excitability may occur, especially in children ■ may cause marked drowsiness	
Drug Facts (continued)	
■ sedatives and tranquilizers may increase drowsiness effect ■ avoid alcoholic beverages ■ use caution when driving a motor vehicle or operating machinery	
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.	
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Questions or Comments? Call 1-844-221-7294 M-F (9 a.m. to 5 p.m. EST)	
Manufactured for: Westminster Pharmaceuticals, LLC. Nashville, TN 373217	
Rev. 07/24	
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PYRILAMINE MALEATE AND DEXTROMETHORPHAN HYDROBROMIDE

pyrilamine maleate and dextromethorphan hydrobromide liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69367-398
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	7.5 mg in 5 mL
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	7.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	APPLE (Candy Apple)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-398-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH DRUG	M012	07/15/2024	

Revised: 8/2024

Westminster Pharmaceuticals, LLC