

RYDEX - brompheniramine maleate, codeine phosphate, pseudoephedrine hydrochloride liquid
Centurion Labs

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.

Rydex Liquid

Drug Facts

Active ingredients

Purpose

(in each 5 mL teaspoonful)

Brompheniramine Maleate 1.33 mg.....Antihistamine

Codeine Phosphate*6.33 mg.....Antitussive

(Cough Suppressant)

*WARNING: May be habit forming

Pseudoephedrine Hydrochloride 10 mg.....Nasal Decongestant

Uses

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

- cough due to minor throat and bronchial irritation
- nasal congestion
- reduces swelling of the nasal passages
- runny nose
- sneezing
- itching of the nose or throat
- itchy, water eyes

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 cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- chronic pulmonary disease or shortness of breath, or children who are taking other drugs
- heart disease
- high blood pressure
- thyroid disease
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

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 marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- cough or nasal congestion persists for more than 1 week, tends to recur, or is accompanied by a fever, rash or persistent headache. These could be signs of a serious condition.
- may cause or aggravate constipation

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:	3 teaspoonfuls (15 mL) every 4 to 6 hours, not to exceed 18 teaspoonfuls in a 24 hour period.
Children 6 to under 12 years of age:	1 1/2 teaspoonfuls (7.5 mL) every 4 to 6 hours, not to exceed 9 teaspoonfuls in a 24 hour period.
Not recommended for children under 6 years of age.	

Other information

Each 5 mL (one teaspoonful) contains: **sodium 2 mg**
Store at 59° - 86°F (15° - 30°C)

Inactive ingredients

Citric Acid, Cotton Candy Flavor, FD and C Red #40, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, and Sorbitol.

Questions? Comments?

Call 1-866-959-4880

Mon. - Fri. (8am - 5pm) CST.

Call your doctor for medical advise about side effects. Serious side effects associated with this product may be reported to this number.

Product Packaging:

Packaging below represents the labeling currently used:

Principal display panel and side panel for 473 mL label:

NDC 23359-023-16

Rydex Liquid

Antihistamine/Antitussive/Nasal Decongestant

Sugar Free/Alcohol Free

Each 5mL (ONE TEASPOONFUL) FOR ORAL ADMINISTRATION CONTAINS:

Brompheniramine Maleate.....1.33 mg

Codeine Phosphate.....6.33 mg

(WARNING: May be habit-forming.)

Pseudoephedrine Hydrochloride.....10 mg

CV

Cotton Candy Flavor

Centurion Labs, LLC

Leading Pharmaceuticals

16 fl. oz. (473 mL)

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

Dispense in a tight, light-resistant container, as defined in the USP/NF, with a child resistant cap.

This package not intended for dispensing to the patient.

Store at 59° - 86°F(15° - 30°C)

Manufactured for:

Centurion Labs, LLC

Birmingham, AL 35243

Rev. 04/10

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NDC 23359-023-16

RYDEX Liquid

Antihistamine • Antitussive
• Nasal Decongestant

Sugar Free • Alcohol Free

EACH 5 mL (ONE TEASPOONFUL) FOR
ORAL ADMINISTRATION CONTAINS:

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Pseudoephedrine Hydrochloride	10 mg

Cotton Candy Flavor

CENTURION Labs, LLC
A DIVISION OF CENTURION PHARMACEUTICALS, INC.

16 fl. oz. (473 mL)

Drug Facts ▶ Lift Here

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Drug Facts (continued)

- heart disease ■ high blood pressure
- thyroid disease ■ diabetes ■ glaucoma
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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:23359-023
Route of Administration	ORAL	DEA Schedule	CV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Brompheniramine Maleate (UNII: IXA7C9ZN03) (Brompheniramine - UNII:H57G17P2FN)	Brompheniramine Maleate	1.33 mg in 5 mL
Codeine Phosphate (UNII: GSL05Y1MN6) (Codeine - UNII:Q830PW7520)	Codeine Phosphate	6.33 mg in 5 mL

Pseudoephedrine Hydrochloride (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F)	Pseudoephedrine Hydrochloride	10 mg in 5 mL
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Product Characteristics

Color		Score	
Shape		Size	
Flavor	COTTON CANDY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23359-023-16	473 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/14/2010	

Labeler - Centurion Labs (806756461)