RYNEX DM- brompheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid
Edwards Pharmaceuticals, Inc

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.

Rynex DM Liquid

Drug Facts

Active ingredients
(in each 5 mL teaspoonful)
Brompheniramine Maleate 1mg
Dextromethorphan Hydrobromide 5 mg
Phenylephrine Hydrochloride 2.5 mg

Purpose

Antihistamine
Antitussive
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 nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation
- 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 to to an enlarged prostate gland
- a cough that lasts or is chronic such as occurs with smoking, asthma or emphysema
- a cough that occurs with too much phlegm (mucus)
- 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 marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- 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. A persistent cough may be a sign of a serious condition.
- new symptoms occur

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the 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 older:	4 teaspoonfuls (20 mL) every 4 hours, not to exceed 24 teaspoonfuls in 24 hours

	in 24 hours.
Children 6 to under 12 years of age:	2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours.
Children under 6 years of age:	Consult a doctor

Other information

Store at 59° - 86°F (15° - 30°C)

Inactive ingredients

Citric Acid, Glycerin, Propylene Glycol, Purified Water, Sodium Citrate, Sodium Saccharin, Sorbitol, Tutti Frutti Flavor.

Questions? Comments?

Call 1-800-543-9560

PRODUCT PACKAGING

The packaging below represents the labeling currently used:

Principal display panel and side panel for 473 mL label:

NDC 00485-0204-16

Rynex DM Liquid

ANTIHISTAMINE • ANTITUSSIVE

NASAL DECONGESTANT

Each 5 mL (one teaspoonful) for oral administration contains:

Brompheniramine Maleate, USP.....1 mg

Dextromethorphan HBr, USP.....5 mg

Phenylephrine HCl, USP.....2.5 mg

ALCOHOL FREE • DYE FREE

GLUTEN FREE • SUGAR FREE

FOR PROFESSIONAL USE ONLY

Tutti-Frutti Flavor

Manufactured for:

EDWARDS

Pharmaceuticals, Inc.

Ripley, MS 38663

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 with a child-resistant cap.

THIS BOTTLE IS NOT TO BE DISPENSED TO THE CONSUMER.

The labeling for this product includes professional labeling which is not intended for use by the general public.

Manufactured for: Edwards Pharmaceuticals, Inc., Ripley, MS 38663

Iss. 01/12

NDC 0485-0204-16

Rynex DM

Antihistamine • Antitussive • Nasal Decongestant

Sugar Free • Alcohol Free • Dye Free • Gluten Free

Each teaspoonful (5 mL) for oral administration contains:

Brompheniramine Maleate ..... 1 mg
Dextromethorphan HBr ..... 5 mg
Phenylephrine HCl ..... 2.5 mg

Tutti-Frutti Flavor

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

Manufactured for:
EDWARDS
Pharmaceuticals, Inc.
Ripley, MS 38663

N 3 04850 20416 9

16oz. (473 mL)

Drug Facts

Active Ingredients (in each 5 mL teaspoonful)	Purpose
Brompheniramine Maleate 1 mg	Antihistamine
Dextromethorphan HBr 5 mg	Antitussive
Phenylephrine HCl 2.5 mg	Nasal Decongestant

Uses temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other respiratory allergies: ■ runny nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes ■ cough due to minor throat and bronchial irritation ■ 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

Do not use this product, unless directed by a doctor, if you have
■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ a persistent or chronic cough that occurs with too much phlegm (mucus) ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes mellitus ■ difficulty in urination due to enlargement of the prostate gland

Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.

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

Drug Facts (continued)

Stop use and ask 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. ■ new symptoms occur

If pregnant or breastfeeding, 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 (20 mL) every 4 hours, not to exceed 24 teaspoonfuls in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age:	2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours, or as directed by a doctor
Children under 6 years of age:	Consult a doctor

Other information

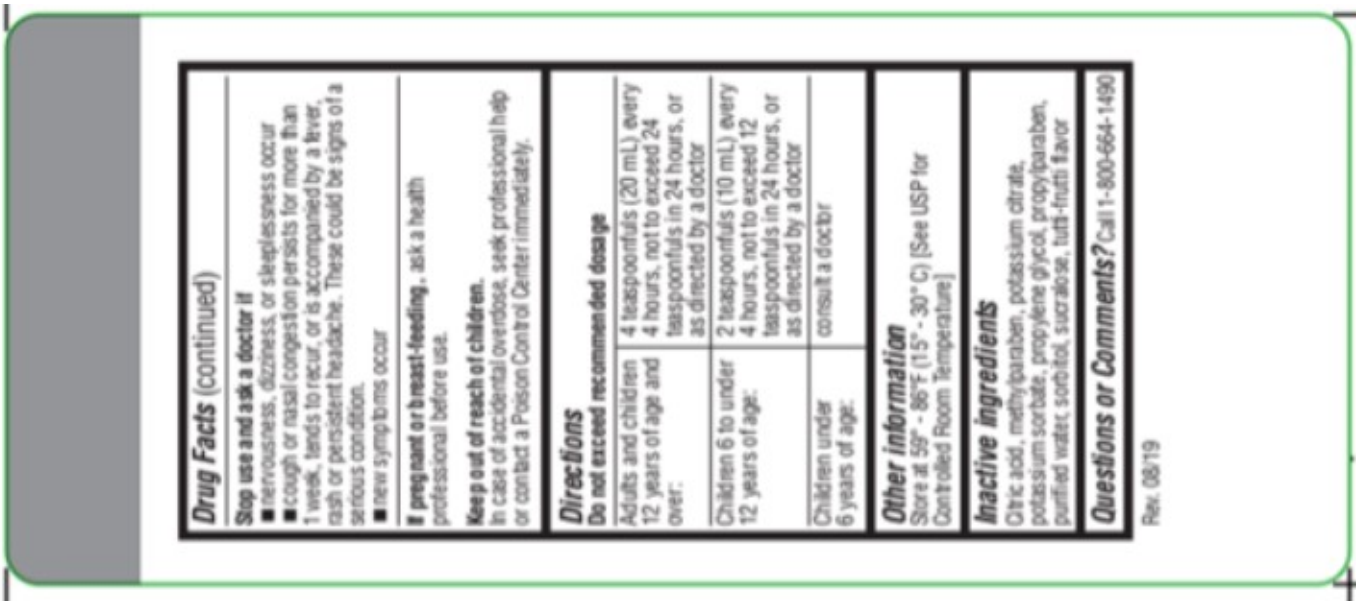
Store at 59° - 86° F (15° - 30° C) [see USP for Controlled Room Temperature].

Inactive ingredients

Citric acid, methylparaben, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water, sorbitol, sucralose, tutti-frutti flavor.

Question? Comments? Call 1-800-543-9560

Rev. 08/19



Drug Facts (continued)

Stop use and ask 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. ■ new symptoms occur

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

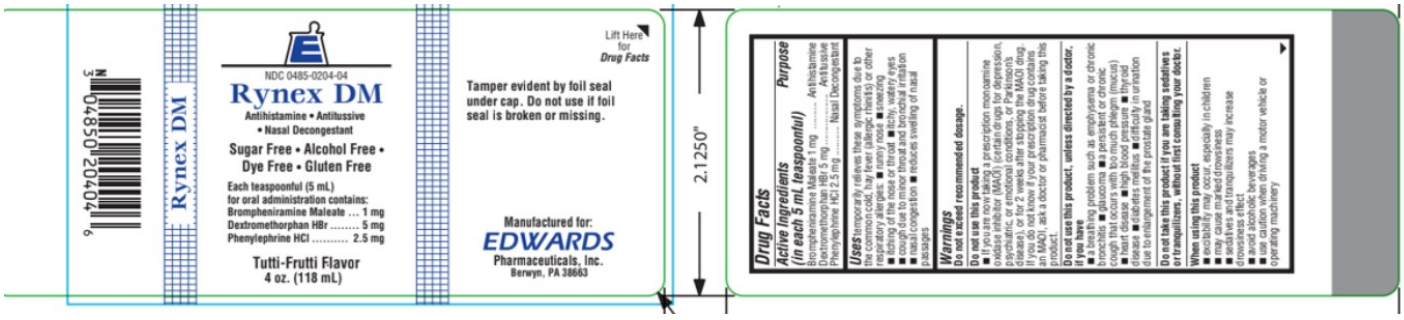
Adults and children 12 years of age and over:	4 teaspoonfuls (20 mL) every 4 hours, not to exceed 24 teaspoonfuls in 24 hours, or as directed by a doctor
Children 6 to under 12 years of age:	2 teaspoonfuls (10 mL) every 4 hours, not to exceed 12 teaspoonfuls in 24 hours, or as directed by a doctor
Children under 6 years of age:	consult a doctor

Other information
Store at 59° - 86°F (15° - 30° C) [See USP for Controlled Room Temperature]

Inactive ingredients
Citric acid, methylparaben, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water, sorbitol, sucralose, tutti-frutti flavor

Questions or Comments? Call 1-800-664-1490

Rev. 08/19



NDC 0485-0204-04

Rynex DM

Antihistamine • Antitussive • Nasal Decongestant

Sugar Free • Alcohol Free • Dye Free • Gluten Free

Each teaspoonful (5 mL) for oral administration contains:
Brompheniramine Maleate ... 1 mg
Dextromethorphan HBr ..... 5 mg
Phenylephrine HCl ..... 2.5 mg

Tutti-Frutti Flavor
4 oz. (118 mL)

Lift Here for Drug Facts

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

Manufactured for:
EDWARDS
Pharmaceuticals, Inc.
Berwyn, PA 38663

2.1250"

Drug Facts
Active Ingredients (in each 5 mL teaspoonful) Purpose
Brompheniramine Maleate 1 mg ..... Antihistamine
Dextromethorphan HBr 5 mg ..... Antitussive
Phenylephrine HCl 2.5 mg ..... Nasal Decongestant

Uses temporarily relieves these symptoms due to the common cold, hay fever (allergic rhinitis) or other respiratory allergies: ■ runny nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes ■ cough due to minor throat and bronchial irritation ■ 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.
Do not use this product, unless directed by a doctor, if you have
■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ a persistent or chronic cough that occurs with too much phlegm (mucus) ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes mellitus ■ difficulty in urination due to enlargement of the prostate gland
Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.
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

RYNEX DM

brompheniramine maleate, dextromethorphan hydrobromide, phenylephrine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0485-0204
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	TUTTI FRUTTI	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0485-0204-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/14/2011	
2	NDC:0485-0204-04	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/14/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/14/2011	

Labeler - Edwards Pharmaceuticals, Inc (195118880)

Revised: 8/2023 Edwards Pharmaceuticals, Inc