BROM TAPP DM- brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid
Rij Pharmaceutical Corporation

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.

Drug Facts

Active Ingredients (in each 5mL tsp)

Brompheniramine maleate, USP 1 mg

Dextromethorphan HBr, USP 5 mg

Phenylephrine HCl , USP 2.5 mg

PURPOSES

Antihistamine

Cough suppressant

Nasal decongestant

USES

- temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold and nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves these symptoms due to hay fever (allergic rhinitis):
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
- temporarily restores freer breathing through the nose

WARNINGS

Do not use

- 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 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
- trouble urinating due to an enlarged prostate gland
- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- cough lasts more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. These could be signs of a serious condition.

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 take more than 6 doses in any 24-hour period

age	dose
adults and children 12 years and over	4 tsp every 4 hours
children 6 to under 12 years	2 tsp every 4 hours
children under 6 years	ask a doctor

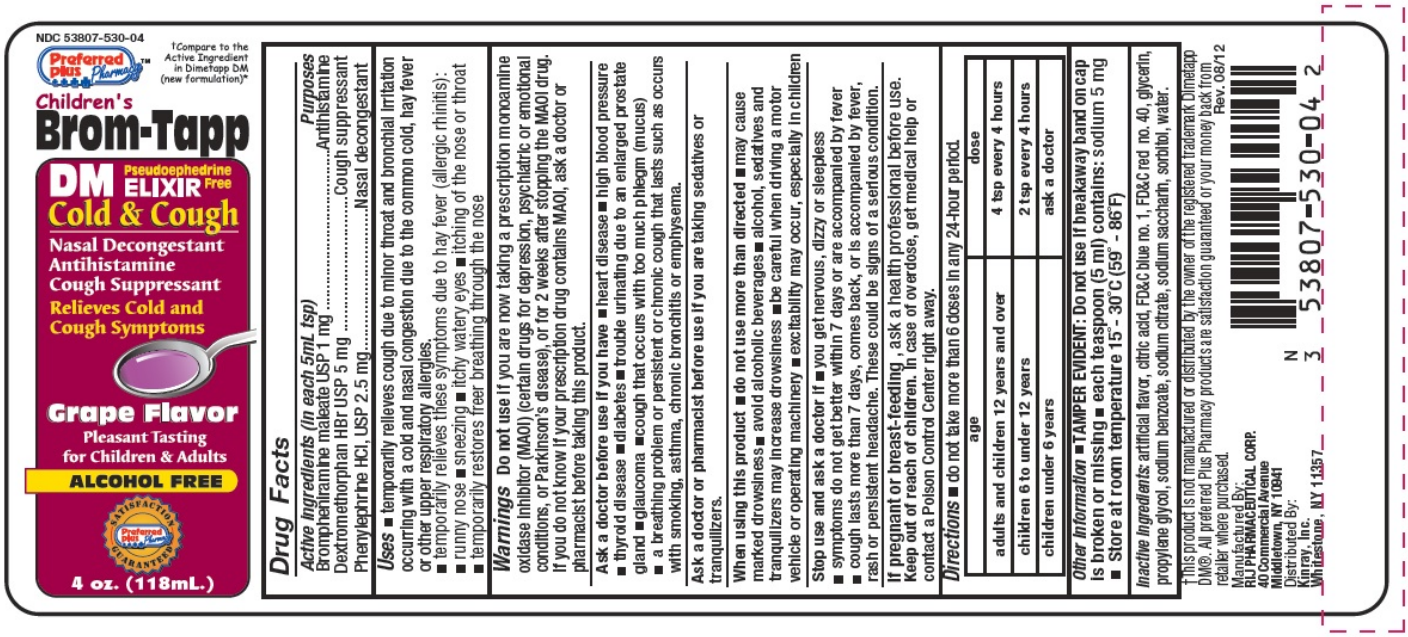
Other Information

- **TAMPER EVIDENT: Do not use if breakaway band on cap is broken or missing**
- each teaspoon (5 ml) contains: sodium 5 mg
- store at room temperature 15º - 30°C (59º - 86°F)

INACTIVE INGREDIENTS

artificial flavor, citric acid, FD&C blue no. 1, FD&C red no. 40, glycerin, propylene glycol, sodium benzoate, sodium citrate, sodium saccharin, sorbitol, water

PRINCIPAL DISPLAY PANEL



BROM TAPP DM

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53807-530
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics			
Color	PURPLE	**Score**	
Shape		**Size**	
Flavor	GRAPE	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-530-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
2	NDC:53807-530-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-530)

Revised: 4/2018 Rij Pharmaceutical Corporation