BROM TAPP- brompheniramine maleate, 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 Phenylephrine HCl , USP 2.5 mg

PURPOSES

Antihistamine

Nasal decongestant

USES

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies associated with sinusitis
- 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
- 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

• do not use more than directed

- drowsiness may occur
- 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

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 15° 30°C (59° 86°F)
- not a USP elixir

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

NDC 53807-529-04 Fredering Children's Broom-Tappo Children's Broom-Tappo ELIXIR Pseudoephedrine Free Cold & Allergy Nasal Decongestant	Purposes Anthistamine Nasal decongestant	stion due to the common cold, hay associated with sinusitis. ue to hay fever (allergic rithintis): eves= fuching of the nose or throat rough the nose	ng a prescription monoamine ssson, psychlatric or emotional ks atter stopping the MAOI drug. tains MAOI, ask a doctor or	lisease m high blood pressure g due to an enlarged prostate as emphysema or chronic	ire taking sedatives or	an directed = drowsiness ol, sedatives and eful when driving a motor ay occur, especially in children	, dizzy or sleepless are accompanied by fever	 ask a health professional before use. case of overdose, get medical help or ight away. 	ny 24-hour period.	dose 4 tsp every 4 hours	2 tsp every 4 hours ask a doctor	t use if breakaway band on cap 5 mi) contains: sodlum 5 mg - 86°F)∎ not a USP elixir	lue no. 1, FD&C red no. 40, glycerin, um saccharin, sorbitol, water.	alted or your more yeak tom alted or your more yeak tom Rev. 06/12 807-529-04 6	
Antihistamine Relieves Cold and Allergy Symptoms Grape Flavor Pleasant Tasting for Children & Adults ALCOHOL FREE 4 oz. (118mL.)	Drug Facts Active ingredients (in each 5mL tsp) Bromphenitamine maleate USP 1 mg Prenyteprinte HCI, USP 2.5 mg	Uses = temporarily relieves nasal congestion due to the common cold, hay tever or other upper respiration allenges associated with sturstis. = temporarily releves these symptoms due to hay fever (allergic minitis): = unity nose = streezing = 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 Takrisons' to steases), 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 mheart disease migh blood pressure a tryrood disease mediabetes m trouble uninating due to an enlarged prostate gland mglaucoma ma breathing problem such as emphysema or chronic bronchitts	Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers.	When using this product = do not use more than directed = drowsiness may occur = 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 a you get nervous, dizzy or sleepless a symptoms do not get better 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 take more than 6 doses In any 24-hour period.	age adults and children 12 years and over	children 6 to under 12 years children under 6 years	ER EVIDENT: Do no sach teaspoon (ure 15° - 30°C (59°	Inactive Ingredients: artiticial flavor, citric acid, FD&C blue no. 1, FD&C red no. 40, glycerin, propytene glycel, sodium benzoate, sodium starcharin, sorbitol, water.	This product is not manufactured or distributed by the owner of the registered trademark Dimetapolities and in pretailer where purplased. The purplased trademark Dimetapolities are satisfaction guarantible or your money back from the registered by the owner of the registered trademark Dimetapolities are satisfaction guarantible or your money back from the registered by the owner of the registered by the owner	

BROM TAPP

brompheniramine maleate, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53807-529
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BRO MPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BRO MPHENIRAMINE - UNII: H57G17P2FN)	BROMPHENIRAMINE MALEATE	1 mg in 5 mL
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDRO US 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	

Col	lor		PURPLE	Score					
Sha	аре			Size					
Fla	vor		GRAPE	Imprint Code					
Contains									
Pa	ckaging								
#	Item Code		Package Description		Marketing Start Date	Marketing End Date			
1 N	NDC:53807-529-04	118 mL in 1 B	OTTLE; Type 0: Not a Combin	ation Product	03/16/1999				
2 N	2 NDC:53807-529-08 236 mL in 1 BOTTLE; Type 0: Not a Comb			ation Product	ition Product 03/16/1999				
M	arketing Info	ormation	ı						
N	/larketing Catego	ry Appli	cation Number or Monogra	ph Citation	Marketing Start Date	Marketing End Date			
ОТ	C MONOGRAPH FIN	AL part341			03/16/1999				

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-529)

Revised: 4/2018

Rij Pharmaceutical Corporation