Q-TAPP DM ELIXIR - brompheniramine maleate and pseudoephedrine hydrochloride and dextromethorphan hydrobromide elixir Preferred 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.

Q-Tapp DM Elixir

Active Ingredient: Brompheniramine maleate 1 mg (in each 5 mL = 1 tsp)

Active Ingredient: Pseudoephedrine hydrochloride 15 mg (in each 5 mL = 1 tsp)

Active Ingredient: Dextromethorphan hydrobromide 5 mg (in each 5 mL = 1 tsp)

Purpose of Brompheniramine maleate: Antihistamine

Purpose of Pseudoephedrine hydrochloride: Nasal Decongestant Purpose of Dextromethorphan hydrobromide: Cough Suppressant

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, or
 associated with sinusitis
- temporarily relieves 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 in children under 6 years of age

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 an 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts or as occurs with smoking, asthma, 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
- marked drowsiness may occur
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsines
- 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 improve 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 4 doses in any 24-hour

Adults and children 12 years and over	20 mL (4 tsp) every 4 to 6 hours
Children 6 years to under 12 years	10 mL (2 tsp) every 4 to 6 hours
Children under 6 years	DO NOT USE

Other information

- each tsp contains: sodium 2 mg
- Store at room temperature 20°-25°C (68°-77°F).

Inactive ingredients

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

Questions

Made in **USA** for Qualitest Pharmaceuticals 130 Vintage Drive Huntsville, AL 35811



Q-TAPP DM ELIXIR

brompheniramine maleate and pseudoephedrine hydrochloride and dextromethorphan hydrobromide elixir

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-0852(NDC:0603-0864)
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		
Pseudoephedrine hydrochloride (UNII: 6 V9 V2RYJ8N) (Pseudoephedrine - UNII:7CUC9 DDI9F)	Pseudo ephedrine hydro chlo ride	15 mg in 5 mL		
Dextromethorphan hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextro methorphan hydro bro mide	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)			
saccharin sodium (UNII: SB8ZUX40TY)			
sodium benzoate (UNII: OJ245FE5EU)			
sodium citrate (UNII: 1Q73Q2JULR)			
sorbitol (UNII: 506T60A25R)			
water (UNII: 059QF0KO0R)			

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	GRAPE (grape flavor)	Imprint Code	
Contains			

Packaging				
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:68788-0852-0	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/05/2001	

Labeler - Preferred Pharmaceuticals, Inc (791119022)

Establishment			
Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc		79 1119 0 22	repack

Revised: 5/2011 Preferred Pharmaceuticals, Inc