

CHILDRENS METAPP DAYTIME- brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid
Guardian Drug Company

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.

Childrens Metapp Daytime Cold and Cough

Active ingredients (in each 5 mL tsp)

Brompheniramine maleate 1 mg

Dextromethorphan HBr 5 mg

Phenylephrine HCl 2.5 mg

Purposes

Antihistamine

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves cough due to minor bronchial irritation as may occur 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):
- sneezing
- itching of the nose or throat
- runny nose
- itchy, watery eyes
- temporarily restores freer breathing through the nose

Warnings

Do not use

- to sedate a child or to make a child sleepy
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI)(certain drugs for depression, psychiatric, or emotional conditions, or parkinsons 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
- glaucoma

- diabetes
- thyroid disease
- high blood pressure
- difficulty in urination due to an enlarged prostate gland
- 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 any other oral nasal decongestant or stimulant
- taking sedatives or tranquilizers

when using this product

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

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- 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 6 doses in any 24-hour period
- do not exceed recommended dosage

Age	Dose
adults and children 12 years and over	4 tsp (20 mL) every 4 hours
children 6 to under 12 years	2 tsp (10 mL) every 4 hours
children under 6 years	do not use

Other information

- each teaspoon (tsp) contains: sodium 5 mg
- store at 20-25°C (68-77°F)
- measuring cup provided

Inactive ingredients

anhydrous citric acid, artificial flavor, FD&C BLUE #1, FD&C red 40, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose

PDP

Compare to the active ingredients in Childrens Dimetapp

Childrens Metapp Daytime

Cold & Cough

Brompheniramine Maleate

Antihistamine

Dextromethorphan HBr

Cough Suppressant

Phenylephrine HCl

Nasal Decongestant

Relieves:

- Nasal Congestion
- Soothes Cough
- Calms allergies

Alcohol Free

For ages 6 years and over

Grape

4 FL OZ (118 mL)



CHILDRENS METAPP DAYTIME

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53041-577
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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:1VS297W6MV)	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)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:53041-577-03	1 in 1 CARTON	06/06/2012	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/06/2012	

Labeler - Guardian Drug Company (119210276)