# EQUATE CHILDRENS MULTI SYMPTOM COLD- dextromethorphan hbr, guaifenesin, phenylephrine hcl solution Wal-Mart Stores 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.

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#### Wal-Mart Childrens Multi-Symptom Cold Drug Facts

# Active ingredients (in each 5 mL)

Dextromethorphan HBr 5 mg Guaifenesin 100 mg Phenylephrine HCl 2.5 mg

# **Purposes**

Cough suppressant

Expectorant

Nasal decongestant

#### Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help your child get to sleep
- nasal congestion due to a cold
- stuffy nose

### Warnings

#### Do not use

in a child who is 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 child's prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

#### Ask a doctor before use if the child has

- heart disease
- high blood pressure
- thyroid disease
- diabetes

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

# When using this product

#### do not use more than directed

#### Stop use and ask a doctor if

- your child gets nervous, dizzy or sleepless
- symptoms do not get better within 7 days or occur with fever
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

#### **Directions**

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter

Age	Dose
children 6 years to under 12 years	10 mL every 4 hours
children 4 years to under 6 years	5 mL every 4 hours
children under 4 years	do not use

# Other information

- each 5 mL contains: sodium 3 mg
- do not use if printed neckband is broken or missing
- store at 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

#### **Inactive ingredients**

anhydrous citric acid, edetate disodium, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

#### **Questions or comments?**

1-888-287-1915

#### Package/Label Principal Display Panel

VALUE PACK

Compare to Children's Mucinex  $^{\mathbb{R}}$  Multi-Symptom Cold active ingredient childrens

MULTI-SYMPTOM COLD

Daytime

Dextromethorphan HBr 5 mg, Cough Suppressant

Guaifenesin 100 mg, Expectorant

Phenylephrine HCl 2.5 mg, Nasal Decongestant

Alcohol-Free

AGES 4 TO 12 YEARS

Relieves:

Stuffy Nose

Cough

**Chest Congestion** 

Breaks Up Mucus

Very Berry

Flavor Liquid

Dosage Cup Included

6.8 FL OZ (201mL)



# EQUATE CHILDRENS MULTI SYMPTOM COLD

dextromethorphan hbr, guaifenesin, phenylephrine hcl solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-524
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	RED (clear)	Score	
Shape		Size	
Flavor	BERRY	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date
1 NDC:49035-524-01	1 in 1 CARTON	08/10/2020	
1	201 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	08/10/2020	

# **Labeler** - Wal-Mart Stores Inc (051957769)

Revised: 8/2020 Wal-Mart Stores Inc