

**DAYTIME NIGHTTIME CHILDRENS MULTI-SYMPATOM COLD- dextromethorphan hbr, guaifenesin, phenylephrine hcl, acetaminophen, diphenhydramine hcl, phenylephrine hcl
Wal-Mart Stores, Inc.**

Daytime Nighttime Children's Multi-Symptom Cold

ACTIVE INGREDIENT(S) FOR DAYTIME (in each 5 mL)

Dextromethorphan HBr 5mg

Guaifenesin 100 mg

Phenylephrine HCl 2.5 mg

ACTIVE INGREDIENT(S) FOR NIGHTTIME (in each 10 mL)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

PURPOSE FOR DAYTIME

Cough Suppressant

Expectorant

Nasal decongestant

PURPOSE FOR NIGHTTIME

Pain reliever/fever reducer

Antihistamine/Cough Suppressant

Nasal decongestant

USE(S)

DAYTIME

- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with a 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

NIGHTTIME

- temporarily relieves these common cold and flu symptoms:
 - cough
 - sore throat
 - nasal congestion
 - runny nose
 - minor aches and pains
 - headache
 - sinus congestion and pressure
 - sneezing
- temporarily reduces fever
- controls cough to help your child get to sleep

WARNINGS

NIGHTTIME

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

DO NOT USE

DAYTIME

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.

NIGHTTIME

- **with any other drug containing acetaminophen** (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- to make a child sleepy
- with any other product containing diphenhydramine, even one used on the skin
- 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 MAOI drug. If you do not know if your child prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

ASK A DOCTOR BEFORE USE IF CHILD HAS

DAYTIME

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

NIGHTTIME

- liver disease
- thyroid disease
- diabetes
- heart disease
- high blood pressure
- glaucoma
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOUR CHILD

NIGHTTIME

- is taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

WHEN USING THIS PRODUCT

DAYTIME

do not use more than directed

NIGHTTIME

- do not use more than directed (**see Overdose warning**)
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

STOP USE AND ASK DOCTOR IF

DAYTIME

- 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 illness.

NIGHTTIME

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 5 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash or headache that lasts. These could be signs of a serious condition.

KEEP OUT OF REACH OF CHILDREN

DAYTIME

In case of overdose, get medical help or contact a Poison Control Center right away.

NIGHTTIME

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical even if you do not notice any signs or symptoms.

DIRECTIONS

DAYTIME

- 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

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

- mL = milliliter

NIGHTTIME

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see Overdose warning)**
- **shake well before use**
- do not give more than 5 doses in any 24-hour period
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 days unless directed by a doctor
- 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
- **children 6 to under 12 years of age:** 10 mL in dosing cup provided.
- **children under 6 years of age:** do not use.

OTHER INFORMATION

DAYTIME

- **each 5 mL contains:** potassium 5 mg, sodium 5 mg
- store between 15-30°C (59-86°F)
- do not refrigerate
- dosing cup provided

NIGHTTIME

- **each 10 mL contains:** sodium 10 mg
- store between 15-30°C (59-86°F)
- do not refrigerate
- dosing cup provided

INACTIVE INGREDIENTS

DAYTIME

citric acid anhydrous, D&C red # 33, dextrose, edetate disodium, FD&C blue # 1, FD&C Red #40, flavor, glycerin, methylparaben, potassium sorbate, propyl gallate, propylene glycol, propylparaben, purified water, saccharin sodium, sodium hydroxide, sorbitol solution, sucralose, xanthan gum.

NIGHTTIME

citric acid anhydrous, edetate disodium, FD&C blue # 1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum.

QUESTIONS OR COMMENTS?

call **1-888-287-1915**

PRINCIPAL DISPLAY PANEL

DAY & NIGHT VALUE PACK

NDC 49035-938-04

equate™

Compare to Children's Mucinex® Multi-Symptom Cold Active Ingredients*

Daytime

Ages 4-12 years

Children's Multi-Symptom Cold

Dextromethorphan HBr 5mg - Cough Suppressant

Guaifenesin 100mg - Expectorant

Phenylephrine HCl 2.5 mg - Nasal Decongestant

- Relieves Stuffy Nose
- Soothes Cough
- Relieves Chest Congestion
- Thins & loosens Mucus

Very Berry Flavored

Dosage cup included

NIGHTTIME

Ages 6-12 years Children's Multi-Symptom Cold Acetaminophen 325mg - Pain reliever/fever reducer Diphenhydramine HCl 12.5mg - Antihistamine/cough suppressant

Phenylephrine HCl 5 mg - Nasal Decongestant

- Temporarily reduces fever
- Soothes cough & sore throat
- Relieves nasal congestion & sneezing

Mixed berry flavored Dosage Cup Included
 TWO 4 FL OZ (118 mL) BOTTLES / 8 FL OZ (236 mL) TOTAL



DAYTIME NIGHTTIME CHILDRENS MULTI-SYMPATOM COLD

dextromethorphan hbr, guaifenesin, phenylephrine hcl, acetaminophen, diphenhydramine hcl, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-938
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49035-938-04	1 in 1 KIT; Type 0: Not a Combination Product	11/26/2024	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	1 BOTTLE	118 mL

Part 1 of 2

CHILDRENS MULTI-SYMPTOM COLD DAYTIME

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Item Code (Source)	NDC:79903-270
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 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)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	BERRY (Verry Berry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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 Drug	M012	11/26/2024	

Part 2 of 2

EQUATE CHILDRENS MULTI SYMPTOM COLD NIGHTTIME

acetaminophen, diphenhydramine hcl, phenylephrine hcl liquid

Product Information

Item Code (Source)	NDC:49035-623
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg in 10 mL
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

GLYCERIN (UNII: PDC6A3C00X)	
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)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor	BERRY (Mixed Berry)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
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 Drug	M012	11/26/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	11/26/2024	

Labeler - Wal-Mart Stores, Inc. (051957769)

Establishment

Name	Address	ID/FEI	Business Operations
Guardian Drug Company		119210276	MANUFACTURE(49035-938)