DAYTIME NIGHTTIME MULTI SYMPTOM COLD CHILDRENS- dextromethorphan hbr,guaifenesin,phenylephrine hcl,acetaminophen,diphenhydramine hcl, phenylephrine hcl
Walgreens

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 for Day Time (in each 5 mL)

Dextromethorphan HBr 5 mg

Guaifenesin 100 mg

Phenylephrine HCl 2.5 mg

Active ingredients for Night Time (in each 10 mL)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purposes for Day Time

Cough suppressant

Expectorant

Nasal decongestant

Purposes for Night Time

Pain reliever/fever reducer

Antihistamine/Cough suppressant

Nasal decongestant

Uses

Daytime

- 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

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

Warnings

Nighttime only

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) (certan 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 childs prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

NIGHTTIME
- with other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- 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.
- with any other drug containing diphenhydramine even one used on the skin
- if your child is allergic to acetaminophen or any of the inactive ingredients in thia product
- to make a child sleepy

Ask a doctor before use your child has

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

NIGHTTIME
- liver disease
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- 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 the child is

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

When using this product

DAYTIME

do not use more than directed.

NIGHTTIME
- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

DAYTIME

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better with 7 days or occur with fever
- cough lasts more than 7 days, comes back, or occurs with a fever, rash, or headache that lasts.These could be signs of a serious condition.

NIGHTTIME

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days
- redness or swelling is present
- new symptoms occur
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with 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 (1-800-222-1222) 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 (1-800-222-1222). Quick medical attention is critical even if you not notice any signs or symptoms.

Directions

DAYTIME

- do not take more than 6 doses in any 24-hour period
- use only the enclosed dosing cup designed for use with this product. Do not use any other dosing device.
- keep dosing cup with product
- 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

NIGHTTIME

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see Overdose warning**)

- 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 any other dosing device
- mL = milliliter
- dose as follows or as directed by a doctor
- children 6 to under 12 years of age: 10 mL every 4 hours
- children under 6 years of age: do not use

Other information

DAYTIME

- **each 5 mL contains:** sodium 5 mg
- store between 20-25ºC (68º-77ºF). Do not refrigerate.

NIGHTTIME

- **each 10 mL contains:** sodium 6 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate.

Inactive ingredients

Inactive ingredients for Daytime

citric acid, disodium EDTA, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Inactive ingredients for Nighttime

citric acid, disodium EDTA, FD&C blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Questions or comments?

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to the active ingredients in Children's Mucinex DayTime Multi-Symptom Cold & Night Time Multi-Symptom Cold††

Children's

MULTI-SYMPTOM COLD

DEXTROMETHORPAN HBr 5 mg / COUGH SUPPRESSANT

GUAIFENESIN 100 mg / EXPECTORANT

PHENYLEPHRINE HCl 2.5 mg / NASAL DECONGESTANT

DAYTIME

ALCOHOL FREE

- Relief from chest congestion, cough & stuffy nose
- Breaks up mucus

AGES 4 - 11 YEARS

Berry flavor

FL OZ (mL)

children's

MULTI-SYMPTOM

ACETAMINOPHEN 325 mg / PAIN RELIEVER / FEVER REDUCER

DIPHENHYDRAMINE HCl 12.5 mg / ANTIHISTAMINE / COUGH SUPPRESSANT

PHENYLEPHRINE HCl 5 mg / NASAL DECONGESTANT

NIGHTTIME

ALCOHOL FREE

- Relief from stuffy nose, cough, fever, sore throat, runny nose & sneezing

AGES 6 - 11 YEARS

Berry flavor

FL OZ (mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL AROUND BOTTLE OR UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

††This product is not manufactured or distributed by Reckitt Benckiser, distributor of Children's Mucinex® Night Time Multi-Symptom Cold and Children's Mucinex® Multi-Symptom Cold.

DISTRIBUTED BY; WALGREEN CO.

DEERFIELD, IL 60015

walgreens.com

Product Label

Walgreens Children's Daytime Nighttime Multi-Symptom Cold Liquid

Walgreens Childrens Daytime Nighttime Multi-Symptom Cold Liquid

DAYTIME NIGHTTIME MULTI SYMPTOM COLD CHILDRENS

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

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0363-4200

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4200-08	1 in 1 KIT; Type 0: Not a Combination Product	12/31/2014	

Quantity of Parts

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

Part 1 of 2

DAYTIME MULTI SYMPTOM COLD CHILDRENS

dextromethorphan hbr,guaifenesin,phenylephrine hcl liquid

Product Information

Item Code (Source)	NDC:0363-4070
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
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)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4070-04	118 mL in 1 BOTTLE, PLASTIC; 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	12/31/2014	

Part 2 of 2

NIGHTTIME MULTI SYMPTOM COLD CHILDRENS

acetaminophen,diphenhydramine hcl,phenylephrine hcl liquid

Product Information	
Item Code (Source)	NDC:0363-4060
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 [arb'U] 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: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color		**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-4060-04	118 mL in 1 BOTTLE, PLASTIC; 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	12/31/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/31/2014	

Labeler - Walgreens (008965063)

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