MULTI SYMPTOM COLD AND MULTI SYMPTOM NIGHTTIME COLD CHILDRENS- dextromethorphan hbr, guaifenesin, phenylephrine hci, acetaminophen, diphenhydramine hci, phenylephrine hci
TARGET Corporation

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 Nighttime (in each 10 mL)

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Active ingredients for Daytime (in each 5 mL)

Dextromethorphan HBr 5 mg

Guaifenesin 100 mg

Phenylephrine HCl 2.5 mg

Purpose for Nighttime

Pain reliever / fever reducer

Antihistamine / Cough suppressant

Nasal Decongestant

Purpose for Daytime

Cough suppressant

Expectorant

Nasal decongestant

Uses

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

Daytime
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make cough more productive
- temporarialy 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

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

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
- in a child who is taking 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 skin.
- If your child is allergic to acetaminophen or any of the inactive ingredients in this product
- to make a child sleepy

Daytime
- in a child who is taking a prescription monoamine oxidase inhibitor (MAOI)(certain drugs for depression,psychiatic 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 giving this product.

Ask a doctor before use if you have

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

Daytime
- 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

Ask a doctor or pharmacist before use if you are

Nighttime
- taking the blood thinning drug warfain
- taking sedative or tranquilizers

When using these products

Nighttime
- **do not use more than directed**
- marked drowsiness may occur
- excitablity may occur, especially in children
- sedatives and tranquilizer may increase drowsiness

Daytime
- **do not use more than directed**

Stop use and ask a doctor if

Nighttime

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or last more than 5 days
- redness or swelling is present
- new symptoms occurs
- 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 conditions.

Daytime

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

Keep out of reach of children.

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 do not notice any sign or symptoms.

Daytime

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

Directions

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

Daytime

- do not take more than 6 doses in any 24-hours 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

Other information

Nighttime

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

Daytime

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

Inactive ingredients

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

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

Questions or comments?

Call **1-800-910-6874**

Principal Display Panel

NIGHTTIME

Compare to active ingredients in Children's Mucinex® Night Time Multi-Symptom Cold*

Children's night time

multi-symptom

Cold Relief

acetaminophen 325 mg (pain reliever / fever reducer)

diphenhydramine HCl 12.5 mg (Antihistamine-Cough Suppressant)

phenylephrine HCl 5 mg (Nasal Decongestant)

relieves

stuffy nose

cough

runny nose and sneezing

fever and sore throat

alcohol free

BERRY FLAVOR

DOSING CUP INCLUDED

AGES 6 - 11 YEARS

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 Multi-Symptom Time Cold

DAYTIME

Compare to active ingredients in Children's Mucinex® Multi-Symptom Cold*

Children's

daytime

multi-symptom cold relief

dextromethorphan HBr 5 mg (Cough Suppressant)

guaifenesin 100 mg (expectorant)

phenylephrine HCl 2.5 mg (Nasal Decongestant)

relieves stuffy nose

controls cough

chest congestion

breaks up mucus

alcohol free

BERRY FLAVOR

DOSING CUP INCLUDED

AGES 4 to 11 YEARS

FL OZ (mL)

Distributed by Target Corporation

Minneapolis, MN 55403

Product Label

TARGET Children's Daytime Nighttime Multi-Symptom Cold Relief

MULTI SYMPTOM COLD AND MULTI SYMPTOM NIGHTTIME COLD CHILDRENS

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-420

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-420-08	1 in 1 KIT; Type 0: Not a Combination Product	02/28/2017	

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

MULTI SYMPTOM COLD DAYTIME CHILDRENS

dextromethorphan hbr, guaifenesin, phenylephrine hci liquid

Product Information

Item Code (Source)	NDC:11673-704
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)	
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
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:11673-704-04	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	02/28/2017	

Part 2 of 2

MULTI SYMPTOM NIGHTTIME COLD CHILDRENS

acetaminophen, diphenhydramine hci, phenylephrine hci liquid

Product Information

Item Code (Source)	NDC:11673-806
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 CALCIUM DISODIUM (UNII: 25IH6R4SGF)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

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:11673-806-04	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	02/28/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/28/2017	

Labeler - TARGET Corporation (006961700)

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