DAYTIME COLD AND COUGH AND NIGHTTIME COLD AND CONGESTION CHILDRENS- brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl, phenylephrine hcl
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)

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Active ingredients for Daytime (in each 10 mL)

Brompheniramine Maleate 2 mg

Dextromethorphan HBr 10mg

Phenylephrine HCl 5 mg

Purpose for Nighttime

Antihistamine / Cough suppressant

Nasal Decongestant

Purpose for Daytime

Antihistamine

Cough suppressant

Nasal decongestant

Uses

Nighttime

- temporarily relieves these symptoms occuring with a cold, hay fever, or other upper respiratory allergies
- nasal congestion
- cough
- runny nose
- sneezing
- itchy, watery eyes

- itching of the nose or throat

Daytime
- temporaily relieves cough due to minor throat and bronchial irritation occuring 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)
  - runny nose
  - itchy, watery eyes
  - sneezing
  - itching of the nose or throat
- temporarily restores freer breathing through the nose

Warnings

Do not use

Nighttime
- 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 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 taking this product
- with any other product containing diphenhydramine, even one used on skin.

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Ask a doctor before use if you have

Nighttime
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- trouble urinating due to an enlarged prostate gland
- cough that occurs with too much phlegm (mucus)
- a breathing problem or chronic cough that last as occurs with smoking,asthma, chronic bronchitis or emphysema

Daytime
- heart disease
- high blood pressure
- thyroid disease

- diabetes
- glaucoma
- trouble urinating due to an enlarged 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

Nighttime
- taking any other oral nasal decongestant or stimulant
- taking sedative or tranquilizers

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When using these products

Nighttime
- **do not use more than directed**
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitablity may occur, especially in children

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- excitability may occur, especially in children

Stop use and ask a doctor if

Nighttime
- you get nervous, dizzy or sleepless
- symptoms do not get better within 7 days or occur with a 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

Daytime
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- 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,

Nighttime

ask a health professional before use.

Daytime

ask a health professional before use

Keep out of reach of children.

Nighttime

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

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Directions

Nighttime

- do not take more than 6 doses in any 24 hours period
- do not exceed recommended dosage
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product
- mL = mililiter

Age	Dose
adults and children 12 years and over	20 mL every 4 hours
childen 6 to under 12 years	10 mL every 4 hours
children under 6 years	**do not use**

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adults and children12 years and over	20 mL every 4 hours
children 6 to under 11 years	10 mL every 4 hours
Children under 6 years	do not use

Other information

Nighttime

- **each 10 mL contains**: sodium 6 mg
- store between 20-25ºC (68-77ºF)
- do not refrigerate
- protect from light

Daytime

- **each 10 mL contains**: 5 mg
- store between 20-25ºC (68-77ºF). Do not refrigerate.

Inactive ingredients

Nighttime

acesulfame potassium, anhydrous citric acid, EDTA disodium, FD&C Blue #1, FD&C red #40, Flavor, maltitol, propylene glycol, purified water, sodium benzoate, trisodium citrate dihydrate

Daytime

citric acid, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose

Questions or comments?

Nighttime

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

Daytime

Call 1-800-910-6874

Principal Display Panel

Compare to active ingredients in Children's Dimetapp® Nighttime Cold & Congestion**

Children's night time

Cold & Congestion

Diphenhydramine HCl 12.5 mg (Antihistamine-Cough Suppressant)

Phenylephrine HCl 5 mg (Nasal Decongestant)

stuffy nose

runny nose

sneezing

itchy,watery eyes

cough

GRAPE FLAVOR

DOSING CUP INCLUDED

AGES 6 + YEARS

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

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

**This product is not manufactured or distributed by Pfizer Consumer Healthcare, distributor of Children's Dimetapp® Nighttime Cold & Congestion.

DAYTIME

Compare to active ingredients in Children's Dimetapp® Cold & Cough*

children's day time

Cold + Cough

Brompheniramine Maleate 2 mg (Antihistamine)

Dextromethorphan HBr 10 mg (Cough Suppressant)

Phenylephrine HCl 5 mg (Nasal Decongestant)

cough

itchy, watery eyes

runny nose

sneezing

stuffy nose

itchy of the nose or throat

alcohol free

GRAPE FLAVOR

DOSING CUP INCLUDED

AGES 6 + YEARS

GRAPE FLAVOR

FL OZ (mL)

*This product is not manufactured or distributed by Pfizer Consumer Healthcare, Distributor of Children's Dimetapp® Cold & Cough.

Distributed by Target Corporation

Minneapolis, MN 55403

Product Label

TARGET Children's Nighttime Cold and Congestion Children's Daytime Cold and Cough

DAYTIME COLD AND COUGH AND NIGHTTIME COLD AND CONGESTION CHILDRENS

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl, diphenhydramine hcl, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11673-059

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-059-08	1 in 1 KIT; Type 0: Not a Combination Product	07/31/2015	

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

NIGHT TIME COLD AND CONGESTION CHILDRENS

diphenhydramine hcl, phenylephrine hcl liquid

Product Information	
Item Code (Source)	NDC:11673-058
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
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**
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MALTITOL (UNII: D65DG142WK)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

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

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:11673-058-04	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	07/31/2015	

Part 2 of 2

DAYTIME COLD AND COUGH CHILDRENS

brompheniramine maleate, dextromethorphan hbr, phenylephrine hcl liquid

Product Information

Item Code (Source)	NDC:11673-613
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BROMPHENIRAMINE MALEATE (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	2 mg in 10 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-613-04	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	07/31/2015	

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/31/2015	

Labeler - TARGET Corporation (006961700)

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