# DAYTIME MUCUS RELIEF SEVERE COLD NIGHTTIME COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl,guaifenesin 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.

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#### **Drug Facts**

# Active ingredients in Daytime (in each softgel) Acetaminophen 325 mg

Dextromethorphan HBr 10 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

### Active ingredients in Nighttime (in each softgel) Acetaminophen 325 mg

Dextromethorphan HBr 10 mg Doxylamine succinate 6.25 mg Phenylephrine HCl 5 mg

# Purpose for Daytime Pain reliever/fever reducer

Cough suppressant Expectorant Nasal decongestant

#### **Purpose for Nighttime**

#### Pain reliever/fever reducer

Cough suppressant

**Antihistamine** 

Nasal decongestant

#### Uses

#### **DAYTIME**

- temporarily relieves these common cold and flu symptoms
  - headache
  - nasal congestion
  - sore throat
  - cough
  - minor aches and pains
  - helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
  - temporarily reduces fever

#### **NIGHTTIME**

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

#### Warnings

#### **DAYTIME and NIGHTTIME**

**Liver warning:** These products contain acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**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 and 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.  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.

#### Ask a doctor before use if you have

#### **DAYTIME**

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

#### **NIGHTTIME**

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

#### Ask a doctor or pharmacist before use if you are

#### **DAYTIME**

taking the blood thinning drug warfarin

#### **NIGHTTIME**

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
- excitability may occur, especially in children
- marked drowsiness may occur
- avoid alcoholic drinks

- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

#### Stop use and ask a doctor if

#### **DAYTIME and NIGHTTIME**

- nervousness, dizziness, or sleeplessness
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

#### If pregnant or breast-feeding,

#### **DAYTIME and NIGHTTIME**

ask a health professional before use.

#### Keep out of reach of children.

#### **DAYTIME and NIGHTTIME**

**Overdose warning**: Taking more than the recommended dose can cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

#### **DAYTIME**

- do not take more than directed (see Overdose warning)
- do not take more than 12 softgels (Daytime and NightTime) in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels every 4 hours
- children under 12 years of age: do not use
- when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

#### NIGHTTIME

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- when using other Daytime or Nighttime products, carefully read each label to ensure correct dosing

#### Other information

#### **DAYTIME** and **NIGHTTIME**

• swallow whole; do not crush, chew, or dissolve

- store between 15-30°C (59-86F)
- avoid excessive heat

#### Inactive ingredients

#### **DAYTIME**

FD&C red #40, FD&C yellow #6, gelatin, glycerin, mannitol\*, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide

\*may contain this ingredient

#### **NIGHTTIME**

D&C yellow #10, FD&C blue #1, gelatin, glycerin, mannitol\*, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sodium hydroxide, sorbitan\*, sorbitol, titanium dioxide

\*contains one or more of these ingredients

#### Question or comments?

Call 1-800-910-6874

#### **Principal Display Panel**

#### **DAYTIME**

Compare to active ingredients in Maximum Strength Mucinex® Fast-Max® Day Severe Cold\*\*\*

maximum strength

daytime severe cold

acetaminophen (pain reliever / fever reducer)

dextromethorphan HBr (cough suppressant)

quaifenesin (expectorant)

phenylephrine HCI (nasal decongestant)

relieves aches, fever and sore throat

controls cough

relieves nasal and chest congestion

thins and loosens mucus

SOFTGELS\*\* (\*\*LIQUID-FILLED CAPSULES)

#### NIGHTTIME

Compare to active ingredients in Maximum Strength Mucinex® Fast-Max® Night Cold & Flu\*\*\*

maximum strength

nighttime

Cold & Flu

acetaminophen (pain reliever / fever reducer)

dextromethorphan HBr (cough suppressant)

doxylamine succinate (antihistamine)

phenylephrine HCI (nasal decongestant)

relieves aches, fever and sore throat

controls cough

relieves nasal congestion

relieves runny nose and sneezing

SOFTGELS\*\* (\*\*LIQUID-FILLED CAPSULES)

\*\*\*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Day Severe Cold and Maximum Strength Mucinex® Fast-Max® Night Cold & Flu.

### TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

## KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Distributed by Target Corporation Minneapolis, MN 55403

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#### **Product Label**



TARGET Maximum Strength Daytime Severe Cold Maximum Strength Nighttime Cold and Flu

# DAYTIME MUCUS RELIEF SEVERE COLD NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl, guaifenesin kit

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:11673-920

ı	Pā	Packaging				
# Item Code Pack		Item Code	Package Description	Marketing Start Date	Marketing End Date	
		NDC:11673-920- 24	1 in 1 KIT; Type 0: Not a Combination Product	12/31/2018	08/29/2025	

Quantity of Parts					
Package Quantity	Total Product Quantity				
8 BLISTER PACK	8				
16 BLISTER PACK	16				
	Package Quantity 8 BLISTER PACK				

#### Part 1 of 2

#### **NIGHTTIME COLD AND FLU MAXIMUM STRENGTH**

acetaminophen, dextromethorphan hydrobromide, doxylamine succinate, phenylephrine hci capsule

#### **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
DOXYLAMINE SUCCINATE (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients				
Ingredient Name	Strength			
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITAN (UNII: 6092ICV9RU)				
SORBITOL (UNII: 506T60A25R)				
SHELLAC (UNII: 46N107B710)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
MANNITOL (UNII: 30WL53L36A)				

<b>Product Characteris</b>	Product Characteristics			
Color	green	Score	no score	
Shape	CAPSULE	Size	20mm	
Flavor		Imprint Code	116;42A	
Contains				

P	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date

1	8 in 1 CARTON
1	1 in 1 BLISTER PACK; 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	12/31/2018	08/29/2025		

#### Part 2 of 2

#### DAYTIME MUCUS RELIEF SEVERE COLD MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci capsule

#### **Product Information**

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		

Inactive Ingredients			
Ingredient Name	Strength		
FD&C RED NO. 40 (UNII: WZB9127XOA)			
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)			
GELATIN (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SORBITAN (UNII: 6O92ICV9RU)			
SORBITOL (UNII: 506T60A25R)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
MANNITOL (UNII: 30WL53L36A)			

#### **Product Characteristics**

Color	orange	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	341;12A
Contains			

Pa	Packaging					
#	# Item Package Description		Marketing Start Date	Marketing End Date		
1		16 in 1 CARTON				
1		1 in 1 BLISTER PACK; 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	12/31/2018	08/29/2025	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	12/31/2018	08/29/2025	

### Labeler - TARGET Corporation (006961700)

Revised: 11/2022 TARGET Corporation