# DAYTIME MUCUS RELIEF SEVERE COLD AND NIGHTTIME COLD AND FLU MAXIMUM STRENGTH- daytime acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hci, nighttime acetaminophen, diphenhydramine hci, phenylephrine hci TARGET Corporation

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#### **DRUG FACTS**

# Active ingredients for Nighttime (in each 20 mL)

### Acetaminophen 650 mg

Diphenhydramine HCI 25 mg

Phenylephrine HCI 10 mg

# Active ingredients for Daytime (in each 20 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifeenesin 400 mg

Phenylephrine HCl 10 mg

# **Purpose for Nighttime**

#### Pain reliever/fever reducer

Antihistamine/cough suppressant

Nasal decongestant

# **Purpose for Daytime**

Pain reliever / fever reducer

Cough suppressant

Expectorant

Nasal decongestant

#### Uses

### **Nighttime**

- temporarily relieves these common cold and flu symptoms
- cough
- nasal congestion
- minor aches and pains

- sore throat
- headache
- runny nose
- sneezing
- temporarily reduces fever
- controls cough to help you get to sleep

#### **Daytime**

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

#### Warnings

#### NIGHTTIME and DAYTIME

**Liver warnin**g: This product 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

# **Nighttime**

- with any drug containing acetaminophen (prescription or nonprescription) . If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other drug containing diphenhydramine, even one used on the skin
- 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

• for children under 12 years of age

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### Ask a doctor before use if you have

## **Nighttime**

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

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- heart disease
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- trouble urinating due to an enlarged gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphtsema
- cough that occurs with too much phlegm (mucus)

# Ask a doctor or pharmacist before use if you are

# **Nighttime**

- you are taking the blood thinning drug warfarin
- you are taking sedative or tranquilizers

# **Daytime**

• taking the blood thinning drug warfarin

# When using these products

# Nighttime

• do not use more than directed

- · excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicile or operating machinery

#### **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 lasts more than 7 days
- fever gets worse, or last 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 a signs of a serious condition

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# If pregnant or breast-feeding,

# **Nighttime and DayTime**

ask a health professional before use.

# Keep out of reach of children.

# **Nighttime and DayTime**

**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 (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**

# **Nighttime**

- do not take more than directed (see overdose warning)
- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device
- keep dosing cup with product

- mL = mililiter
- dose as follows or as directed by a doctor
- adults and children 12 years and older: 20 mL every 4 hours while symptoms last
- children under 12 years of age: do not use

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- mL = milliliter
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#### Other information

## **Nighttime**

- each 20 mL contains: sodium 12 mg
- store between 20-25°C (68-77°F). Do not refrigerate.

### **Daytime**

- each 20 mL contains: 12 mg
- store between 20-25°C (68-77°F). 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 blue #1, FD&C red #40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

# **Principal Display Panel**

#### **NIGHTTIME**

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

maximum strength

# nighttime

#### Cold & Flu

acetaminophen (pain reliever / fever reducer)

diphenhydramine HCI (antihistamine / cough suppressant)

phenylephrine HCI (nasal decongestant)

Relieves aches, fever, sore throat

controls cough

relieves nasal congestion

relieves runny nose and sneezing

AGES 12 + YEARS

#### **DAYTIME**

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

maximum strength

daytime

Severe Cold

acetaminophen (pain reliever / fever reducer)

dextromethorphan HBr (cough suppressant)

guaifenesin (expectorant)

phenylephrine HCI (nasal decongestant)

Relieves aches, fever & sore throat

Controls Cough

relieves nasal and chest congestion

thins and loosens mucus

AGES 12 + YEARS

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

\*This prodect is not manufactured or distributed by Recitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Day Time Severe Cold.

\*\*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® FAST-MAX® Night Time Cold & Flu.

Dist. by Target Corp.

Minneapolis, MN 55403

Product of U.S.A.

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#### **Product Label**



TARGET Maximum Strength Nighttime cold and flu Maximum Strength Daytime Severe Cold

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

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

Product Information				
<b>Product Type</b>	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-463	

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:11673-463- 12	1 in 1 KIT; Type 0: Not a Combination Product	01/11/2018	

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	1 BOTTLE, PLASTIC	177 mL		
Part 2	1 BOTTLE, PLASTIC	177 mL		

#### Part 1 of 2

### MUCUS RELIEF SEVERE COLD DAYTIME MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

# **Product Information**

Item Code (Source) NDC:11673-410

**Route of Administration** ORAL

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 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)		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYL GALLATE (UNII: 8D4SNN7V92)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
XANTHAN GUM (UNII: TTV12P4NEE)		

l	Pa	Packaging				
	#	ltem Code	Package Description	Marketing Start Date	Marketing End Date	
	1		177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product			

Marketing Information				
Marketing Application Number or Monograph Marketing Start Marketing End Category Citation Date Date				
OTC Monograph Drug	M012	01/11/2018	01/11/2026	

# Part 2 of 2

# NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, diphenhydramine hci, phenylephrine hci liquid

#### **Product Information**

Item Code (Source) NDC:11673-460

**Route of Administration** ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg in 20 mL		
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg in 20 mL		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 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)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
PROPYL GALLATE (UNII: 8D4SNN7V92)			
XANTHAN GUM (UNII: TTV12P4NEE)			
EDETATE CALCIUM DISODIUM (UNII: 25IH6R4SGF)			

l	Pa	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1		177 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 Drug	M012	01/11/2018	01/11/2026		

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	01/11/2018		

# Labeler - TARGET Corporation (006961700)

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