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

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

- 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

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

Questions or comments?

DAYTIME and NIGHTTIME

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

Principal Display Panel

Compare to Maximum Strength Mucinex® Fast-Max® Day Severe Cold & Maximum Strength Mucinex® Fast-Max® Night Cold & Flu active ingredients††

DAYTIME

Severe Cold

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

GUAIFENESIN / EXPECTORANT

PHENYLEPHRINE HCI / NASAL DECONGESTANT

MAXIMUM STRENGTH

ALCOHOL FREE

- Relieves aches, fever & sore throat
- Controls cough
- Thins & loosens mucus
- Clears nasal & chest congestion
- Ages 12 & over

SOFTGELS*

(*LIQUID-FILLED CAPSULES)

NIGHTTIME

Cold & Flu

ACETAMINOPHEN / PAIN RELIEVER / FEVER REDUCER

DEXTROMETHORPHAN HBr / COUGH SUPPRESSANT

DOXYLAMINE SUCCINATE / ANTIHISTAMINE

PHENYLEPHRINE HCI / NASAL DECONGESTANT

MAXIMUM STRENGTH

ALCOHOL FREE

- Relieves aches, fever & sore throat, nasal congestion, runny nose & sneezing
- Controls cough
- Ages 12 years & over

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: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

Product Label



WALGREENS Daytime Severe Cold Nighttime Cold & Flu

DAYTIME MUCUS RELIEF SEVERE COLD NIGHTTIME COLD AND FLU MAXIMUM STRENGTH

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

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0363-0820 **Packaging Marketing Start Marketing End Item Code Package Description Date Date** NDC:0363-0820-1 in 1 KIT; Type 0: Not a Combination 1 09/30/2018 09/30/2025 Product

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	8 BLISTER PACK	8		
Part 2	16 BLISTER PACK	16		
rait 2	10 BLISTER FACE	10		

Part 1 of 2

Product Information

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		
DEXTROMETHORPHAN HYDROBROMIDE (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)			

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

Ш	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		

1	L	8 in 1 CARTON
1	L	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 Drug	M012	09/30/2018	09/30/2025		

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		
DEXTROMETHORPHAN HYDROBROMIDE (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: 6092ICV9RU)		
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 Code	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 Drug	M012	09/30/2018	09/30/2025		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	09/30/2018	09/30/2025

Labeler - Walgreens (008965063)

Revised: 7/2024 Walgreens