MUCINEX NIGHTSHIFT SEVERE COLD AND FLU MAXIMUM STRENGTHacetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride tablet, coated RB Health (US) LLC

-----

Mucinex® Nightshift Severe Cold & Flu

## **Maximum Strength**

## **Drug Facts**

Active ingredients (in each caplet)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant
Triprolidine HCl 1.25 mg	Antihistamine

#### Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - sinus congestion and pressure
  - runny nose
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

#### Warnings

# Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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

- 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

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- 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, or emphysema
- cough that occurs with too much phlegm (mucus)

# Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

# When using this product

- 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
- use caution when driving a motor vehicle or operating machinery

# Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- 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 fever, rash, or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

## **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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

#### **Directions**

- do not take more than directed (see Overdose warning)
- do not take more than 8 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

#### Other information

store at 20-25°C (68-77°F)

# Inactive ingredients

croscarmellose sodium, crospovidone, ferric oxide, hydroxypropyl cellulose, mica, microcrystalline cellulose, polyvinyl alcohol, polyvinyl alcohol polyethylene glycol copolymer, povidone, silicon dioxide, stearic acid, talc, titanium dioxide

Dist. by: RB Health (US) Parsippany, NJ 07054-0224

# PRINCIPAL DISPLAY PANEL - 20 Caplet Blister Pack Carton

FAST RELEASE. POWERFUL SYMPTOM RELIEF!

NDC 72854-234-20

MAXIMUM STRENGTH Mucinex® NIGHTSHIFT

SEVERE COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer Dextromethorphan HBr – Cough Suppressant Phenylephrine HCl – Nasal Decongestant Triprolidine HCl – Antihistamine ALL IN ONE\*

HEADACHE SORE THROAT ITCHY THROAT

BODY PAIN FEVER COUGH

**NASAL CONGESTION** 

SNEEZING RUNNY NOSE

**ACTUAL SIZE** 

20 CAPLETS

FOR AGES 12+

FAST RELEASE MAXIMUM STRENGTH

Tamper evident: Do not use if carton is damaged or if printed seal on blister is broken or missing.



**SEVERE COLD & FLU** 

FAST RELEASE. POWERFUL SYMPTOM RELIEF

MAXIMUM STRENGTH

NDC 72854-234-20



# **SEVERE COLD & FLU**

Acetaminophen - Pain Reliever/Fever Reducer Dextromethorphan HBr - Cough Suppressant Phenylephrine HCI - Nasal Decongestant Triprolidine HCI - Antihistamine



**ACTUAL SIZE** 

**20 CAPLETS** 

FOR AGES 12+

**FAST** 

RELEASE

LOT:

EXP.:

MADE IN:

3176311



3176311



MAXIMUM STRENGTH

chase
\*Helps to relieve these
symptoms at right
Do not take more than a total of
8 caplets in any 24-hour period.

Strength per

4-hou

# Drug Facts

#### Active ingredients (in each caplet)

# Acetaminophen 325 mg............Pain reliever/fever reducer

Purposes

#### Dextromethorphan HBr 10 mg......Cough suppressant Phenylephrine HCl 5 mg......Nasal decongestant Triprolidine HCl 1.25 mg......Antihistamine

- temporarily relieves these common cold and flu symptoms:
- nasal congestion
- minor aches and pains sore throat
- headache
- sinus congestion and pressure
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

#### Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy a lert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- If a skin reaction occurs, stop use and seek medical help right

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

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains a cetamin ophen, 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 stooping 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

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- daucoma
- trouble urinating due to an enlarged prostate gland

#### Drug Facts (continued)

- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking. asthma, or emphysema
- cough that occurs with too much phiegm (mucus)

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

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

#### When using this product

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

#### Stop use and ask a doctor if

- nervousness, dizziness, or slee plessness occur
- 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 fever, rash, or headache that lasts. These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

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. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

- do not take more than directed (see Overdose warning)
- do not take more than 8 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

## Other information

store at 20-25°C (68-77°F)

Inactive ingredients croscarmellose sodium, crospovidone, ferric oxide, hydroxypropyl cellulose, mica, microcrystalline cellulose, polyvinyl alcohol, polyvinyl alcohol polyethylene glycol copolymer, povidone, silicon dioxide, stearic acid, talc, titanium dioxide

# MUCINEX NIGHTSHIFT SEVERE COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-234
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		
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII: 2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg		

Inactive Ingredients				
Ingredient Name	Strength			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
CROSPOVIDONE (UNII: 2S7830E561)				
FERRIC OXIDE RED (UNII: 1K09F3G675)				
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)				
MICA (UNII: V8A1AW0880)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POLYVINYL ALCOHOL GRAFT POLYETHYLENE GLYCOL COPOLYMER (3:1; 45000 MW) (UNII: 23ZQ42JZZH)				
POVIDONE, UNSPECIFIED (UNII: FZ 989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				

Product Characteristics			
Color	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	VW;LOGOcres centmoonplus
Contains			

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72854- 234-20	2 in 1 CARTON	07/01/2021		
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:72854- 234-02	2 in 1 PACKET; Type 0: Not a Combination Product	07/01/2021		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	07/01/2021		

# Labeler - RB Health (US) LLC (081049410)

Revised: 10/2023 RB Health (US) LLC