

**NIGHTTIME COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled**  
**QUALITY CHOICE (Chain Drug Marketing Association)**

*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 each softgel)**

#### **Acetaminophen 325 mg**

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCl 5 mg

## **Purposes**

### **Pain reliever/fever reducer**

Cough suppressant

Antihistamine

Nasal decongestant

## **Uses**

- 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**

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

- more than 4,000 of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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
- diabetes
- high blood pressure
- heart disease
- glaucoma
- thyroid
- trouble urinating due to an enlarged prostate gland
- breathing problems 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)

**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
- 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**

- 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 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 12 softgels 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

**Other information**

- store between 20-25°C (68-77°F)
- avoid excessive heat
- swallow whole; do not crush, chew, or dissolve

**Inactive ingredients**

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

**Questions or comments?**

Call **1-800-935-2362** Monday-Friday 9AM-5PM EST

**Principal Display Panel**

Compare to the Active Ingredients in Mucinex® Maximum Strength Fast-Max® Night Cold & Flu

Maximum Strength

Nighttime

Cold & Flu

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Doxylamine succinate 6.25 mg

Phenylephrine HCL 5 mg

Pain Reliever | Fever Reducer | Cough Suppressant

Antihistamine | Nasal Decongestant

Relieves Aches, Fever & Sore Throat

Controls Cough

Relieves Nasal Congestion

Relieves Runny Nose & Sneezing

For Ages 12 Years and Older

Alcohol-Free

Softgels\*\*

(\*\*Liquid-Filled Capsules))

**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.**

†This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Night Cold, Flu Liquid Gels

Distributed by C.D.M.A., Inc, ©

43157 W 9 Mile Rd

Novi, MI 48375

[www.qualitychoice.com](http://www.qualitychoice.com)

**Package Label**

<p><b>Drug Facts</b></p> <p><b>Active ingredients (in each softgel)</b>    <b>Purposes</b></p> <p>Acetaminophen 325 mg.....Pain reliever/fever reducer</p> <p>Dextromethorphan HBr 10 mg.....Cough suppressant</p> <p>Doxylamine succinate 6.25 mg.....Antihistamine</p> <p>Phenylephrine HCl 5 mg.....Nasal decongestant</p> <p><b>Uses</b>    ■ 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</p> <p><b>Warnings</b></p> <p><b>Liver warning:</b> This product contains 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</p> <p><b>Allergy alert:</b> 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.</p> <p><b>Sore throat warning:</b> 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.</p> <p><b>Do not use</b>    ■ 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.</p> <p><b>Ask a doctor before use if you have</b></p> <p>■ liver disease    ■ diabetes    ■ high blood pressure  ■ heart disease    ■ glaucoma    ■ thyroid disease  ■ trouble urinating due to an enlarged prostate gland  ■ breathing problems 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)</p>	<p><b>Drug Facts (continued)</b></p> <p>Ask a doctor or pharmacist before use if you are</p> <p>■ taking the blood thinning drug warfarin  ■ taking sedatives or tranquilizers</p> <p><b>When using this product</b>    ■ 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</p> <p><b>Stop use and ask a doctor if</b>    ■ 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 rash or headache that lasts. These could be signs of a serious condition.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning:</b> 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.</p> <p><b>Directions</b>    ■ do not take more than directed (see Overdose warning)    ■ do not take more than 12 softgels 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</p> <p><b>Other information</b></p> <p>■ store between 20-25°C (68-77°F)    ■ avoid excessive heat    ■ swallow whole; do not crush, chew, or dissolve</p> <p><b>Inactive ingredients</b> D&amp;C yellow #10, FD&amp;C blue #1, gelatin, glycerin, mannitol, polyethylene glycol, povidone, propylene glycol, purified water, sorbitan, sorbitol, titanium dioxide</p> <p><b>Questions or comments?</b>  Call 1-800-935-2362 Monday-Friday 9AM-5PM EST</p>
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\*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Night Cold & Flu Liquid Gels.

**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.**

**PARENTS:**  
**Read and understand this information.**  
[www.StopMedicine Abuse.org](http://www.StopMedicine Abuse.org)

NDC 63868-672-16



**Maximum Strength  
Nighttime  
Cold & Flu**

**Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Doxylamine succinate 6.25 mg  
Phenylephrine HCl 5 mg**

Pain Reliever | Fever Reducer | Cough Suppressant  
Antihistamine | Nasal Decongestant

Relieves Aches, Fever & Sore Throat  
Controls Cough  
Relieves Nasal Congestion  
Relieves Runny Nose & Sneezing

For Ages 12 Years and Older  
Alcohol-Free



**16 Softgels\*\* (\*\*Liquid-Filled Capsules)**

1Compare to the Active Ingredients in Mucinex® Maximum Strength Fast-Max® Night Cold & Flu

actual size



Distributed by C.D.M.A., Inc.  
43157 W 9 Mile Rd  
Novi, MI 48375  
www.qualitychoice.com  
Questions: 800-935-2362



PLD-A592A FC005938

Lot No:  
Exp. Date:

**QUALITY CHOICE Maximum Strength Nighttime Cold & Flu**

<b>NIGHTTIME COLD AND FLU MAXIMUM STRENGTH</b>			
acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hcl capsule, liquid filled			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-672
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)		DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)		PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)		DOXYLAMINE SUCCINATE	6.25 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MANNITOL</b> (UNII: 3OWL53L36A)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-672-16	16 in 1 CARTON	07/31/2018	07/31/2025
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	07/31/2018	07/31/2025

**Labeler** - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 5/2023

QUALITY CHOICE (Chain Drug Marketing Association)