

COLD FLU AND SORE THROAT MAXIMUM STRENGTH- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)

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.

Drug Facts

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

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

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
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- 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.

When using this product,

do not use more than directed.

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 (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

- **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

- swallow whole: do not crush, chew, or dissolve
- avoid excessive heat
- store between 15-30°C (59-86°F)

Inactive ingredients

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

*may contain this ingredient

Questions or comments?

Call **1-888-309-9030**

Principal Display Panel

Compare to the active ingredients of Maximum Strength Mucinex® Fast-Max® Cold, Flu, & Sore Throat**

For Ages 12 & Over

Maximum Strength

Mucus Relief

Cold, Flu & Sore Throat

Acetaminophen 325 mg Pain reliever /Fever reducer

Dextromethorphan HBr 10 mg Cough Suppressant

Guaifenesin 200 mg Expectorant

Phenylephrine HCl 5 mg Nasal Decongestant :

- Controls cough, thins & loosen mucus
- Relieves nasal & chest congestion
- Relieves headache & fever

Alcohol-free

Softgels

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® Cold, Flu & Sore Throat.

DISTRIBUTED BY DOLGENCORP, LLC

100 MISSION RIDGE

GOODLETTSVILLE, TN 37072

Package Label

Drug Facts		Drug Facts (continued)	
Active ingredients (in each softgel)	Purposes	Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.	
Acetaminophen 325 mg	Pain reliever/fever reducer	When using this product, do not use more than directed.	
Dextromethorphan HBr 10 mg	Cough suppressant	Stop use and ask a doctor if	
Guaifenesin 200 mg	Expectorant	<ul style="list-style-type: none"> 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. 	
Phenylephrine HCl 5 mg	Nasal decongestant	<ul style="list-style-type: none"> If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. 	
Uses		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.	
<ul style="list-style-type: none"> temporarily relieves these common cold and flu symptoms <ul style="list-style-type: none"> headache nasal congestion sore throat cough minor aches and pains temporarily reduces fever helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive. 		Directions	
Warnings		<ul style="list-style-type: none"> 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 	
<ul style="list-style-type: none"> Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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) 		Other information	
		<ul style="list-style-type: none"> swallow whole; do not crush, chew, or dissolve avoid excessive heat store between 15-30°C (59-86°F) 	
		Inactive ingredients 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	
		Questions or comments? Call 1-888-309-9030	
		**This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Cold, Flu & Sore Throat.	
		<p style="text-align: center;">TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS TURN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.</p> <p style="text-align: center;">KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.</p>	

Maximum Strength
Mucus Relief
Cold, Flu & Sore Throat



Compare to the active ingredients of Maximum Strength Mucinex® Fast-Max® Cold, Flu & Sore Throat™

For Ages 12 & Over

Maximum Strength

Mucus Relief

Cold, Flu & Sore Throat

Acetaminophen 325 mg
Pain Reliever/Fever Reducer
Dextromethorphan HBr 10 mg
Cough Suppressant
Guaifenesin 200 mg/Expectorant
Phenylephrine HCl 5 mg/Nasal Decongestant

- Controls cough, thins & loosens mucus
- Relieves nasal & chest congestion
- Relieves headache & fever

Alcohol-free



16 Softgels

Actual Size



DISTRIBUTED BY DOLGENCORP, LLC
100 MISSION RIDGE
GOODLETTSVILLE, TN 37072

100% Satisfaction Guaranteed!
(888) 309-9030

PARENTS: Learn about your medicine at www.StopMedicinePoison.org

Lot No.:
Exp. Date:

DOLLAR GENERAL HEALTH Maximum Strength Mucus Relief Cold, Flu & Sore Throat

COLD FLU AND SORE THROAT MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-838
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE (UNII: FZ989GH94E)	
SORBITAN (UNII: 6O92ICV9RU)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MANNITOL (UNII: 3OWL53L36A)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-838-16	16 in 1 CARTON	01/31/2019	01/31/2025
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	01/31/2019	01/31/2025

Labeler - Dolgencorp, Inc. (DOLLAR GENERAL & REXALL) (068331990)

Revised: 10/2022

Dolgencorp, Inc. (DOLLAR GENERAL & REXALL)