TOPCARE MUCUS RELIEF SEVERE CONGESTION AND COLD- acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated
Topco Associates LLC

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.

Topco Associates LLC. Mucus Relief Severe Congestion & Cold Drug Facts

Active ingredients (in each caplet)

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:
- nasal congestion
- headache
- cough
- minor aches and pains
- sore throat
- temporary 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 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

- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- 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 persistent headache. 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 10 caplets in any 24-hour period
- adults and children 12 years and older: take 2 caplets every 4 hours
- children under 12 years of age: do not use

Other information

- **each caplet contains:** sodium 4 mg
- store at 20-25°C (68-77°F)
- do not use if blister unit is broken or torn

Inactive ingredients

croscarmellose sodium, crospovidone, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

MAXIMUM STRENGTH**

FOR AGES 12+

COMPARE TO MUCINEX® FAST-MAX® SEVERE COLD CAPLETS ACTIVE INGREDIENTS

MAXIMUM STRENGTH**

Mucus Relief

Severe Congestion & Cold

PAIN RELIEVER - FEVER REDUCER - ACETAMINOPHEN

COUGH SUPPRESSANT - DEXTROMETHORPHAN HBr

EXPECTORANT - GUAIFENESIN

NASAL DECONGESTANT - PHENYLEPHRINE HCl

OUR PHARMACISTS RECOMMEND

Relieves Aches, Fever & Sore Throat

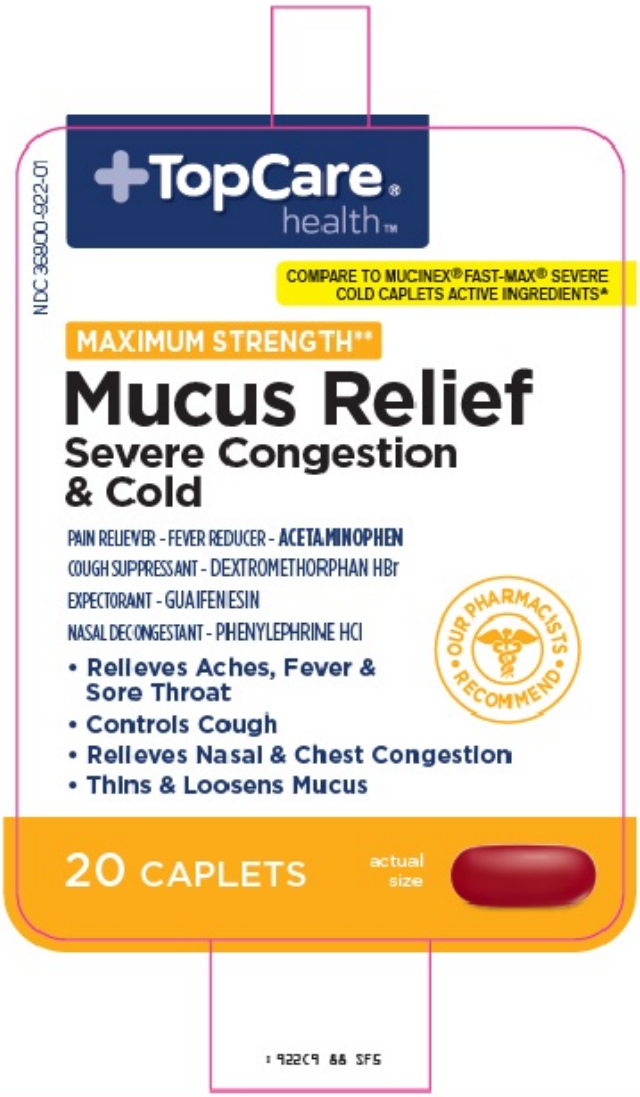
Controls Cough

Relieves Nasal & Chest Congestion

Thins & Loosens Mucus

20 CAPLETS

actual size


TopCare health
NDC 36800-922-01
COMPARE TO MUCINEX® FAST-MAX® SEVERE COLD CAPLETS ACTIVE INGREDIENTS*
MAXIMUM STRENGTH**
Mucus Relief
Severe Congestion & Cold
PAIN RELIEVER - FEVER REDUCER - ACETAMINOPHEN
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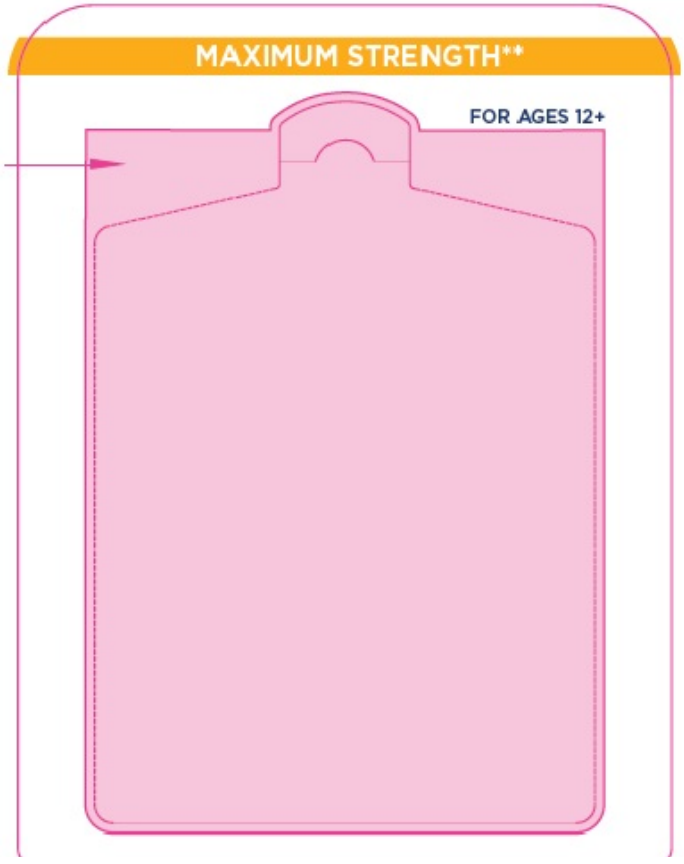
20 CAPLETS
actual size
: 922C9 88 SF5


MAXIMUM STRENGTH**
FOR AGES 12+


PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org
This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.
DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
©TOPCO PERRLY QUESTIONS? 1-888-423-0130
topcare@topco.com www.topcarebrand.com
**Per 4-hour dose, dose every 4 hours
Keep outer package for complete product information.
Lift here to open
0 36800 37577 2
GLUTEN FREE
Drug Facts
Active Ingredients (in each caplet) Purposes
Acetaminophen 325 mg ..... Pain reliever/fever reducer
Dextromethorphan HBr 10 mg ..... Cough suppressant
Guaifenesin 200 mg ..... Expectorant
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Ask a doctor before use if you have
■ liver disease ■ heart disease ■ diabetes
Drug Facts (continued)
■ high blood pressure ■ 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
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■ pain, nasal congestion or cough gets worse or lasts more than 7 days
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■ 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.
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Questions or comments? 1-888-423-0130
*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Fast-Max® Severe Cold Caplets.
: 922C9 88 SB4

TOPCARE MUCUS RELIEF SEVERE CONGESTION AND COLD

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:36800-922
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	**Score**	no score
Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	L922
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-922-01	10 in 1 CARTON	06/28/2013	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2	NDC:36800-922-39	15 in 1 CARTON	06/28/2013	
2		2 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	06/28/2013	

Labeler - Topco Associates LLC (006935977)

Revised: 12/2019 Topco Associates LLC