FAST MUCUS RELIEF- acetaminophen, dextromethporphan hydrobromide, guaifenes in, phenylephrine hydrochloride solution Kroger Company

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.

Kroger Co. Fast Mucus Relief Drug Facts

Active ingredients (in each 20 mL)

Acetaminophen 650 mg
Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer Cough suppressant Expectorant Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
- cough
- nasal congestion
- minor aches and pains
- sore throat
- headache
- temporarily reduces fever
- temporarily promotes nasal and/or sinus drainage
- 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
- high blood pressure
- thyroid disease
- diabetes
- 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: 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 5 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other information

- each 20 mL contains: sodium 7 mg
- dosing cup provided
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

anhydrous citric acid, benzyl alcohol, edetate disodium, FD&C blue #1, FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triethyl citrate, xanthan gum

Questions or comments?

1-800-632-6900

Package/Label Principal Display Panel

COMPARE TO the active ingredients of MUCINEX® FAST-MAX® COLD, FLU & SORE THROAT See back panel

OUR PHARMACIST RECOMMENDED

for ages 12+

Maximum Strength

FAST

Mucus Relief

Cold, Flu & Sore Throat

Acetaminophen

Pain Reliever/Fever Reducer

Dextromethorphan HBr

Cough Suppressant

Guaifenesin

Expectorant

Phenylephrine HCl

Nasal Decongestant

RELIEVES

Headache, Fever & Sore Throat

Nasal & Chest Congestion

Controls Cough

Thins & Loosens Mucus

6 FL OZ (180 mL)





Drug Facts (continued) 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 5 doses in any 24-hour period measure only with dosing cup provided
do not use dosing cup with other products dose as follows or as directed by a doctor ■ adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours ■ children under 12 years of age: do not use Other information ■ each 20 mL contains: sodium 7 mg ■ dosing cup provided ■ store at 20-25°C (68-77°F) ■ do not refrigerate Inactive ingredients anhydrous citric acid, benzyl alcohol, edetate disodium, FD&C blue #1. FD&C red #40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, triethyl citrate, xanthan gum Questions or comments? 1-800-632-6900 "Mucinex* and Fast-Max* are reg trademarks of RB Health (US) LLC, Parsipporty NJ 07054. RB Health (US) LLC is not affiliated with The Kroger Co. or this product

Drug Facts (continued) 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 emptysema 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 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.

FAST MUCUS RELIEF

acetaminophen, dextromethporphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-572
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	650 mg in 20 mL	
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL	
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)		
SORBITOL (UNII: 506T60A25R)		
SUCRALOSE (UNII: 96K6UQ3ZD4)		
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)		
XANTHAN GUM (UNII: TTV12P4NEE)		

Product Characteristics			
Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

	Packaging				
ı	# I	tem Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC	:30142-572-30	180 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/09/2019	

	Marketing Infor	keting Information			
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	

OTC monograph final part341 05/09/2019

Labeler - Kroger Company (006999528)

Revised: 4/2020 Kroger Company