SEVERE CONGESTION AND COUGH RELIEF- dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid Safeway

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.

Maximum Strength Severe Congestion and Cough Relief

Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purpose

Cough suppressant

Expectorant

Nasal decongestant

Uses

- helps loosen phelgm (mucus) and thin bronchial secretions to drain bronchial tubes and make coughs more productive
- temporarily relieves:
- cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
- the intensity of coughing
- the impulse to cough to help you get to sleep
- nasal congestion due to a cold

Warnings

Do not use

- for children under 12 years of age
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for 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

- 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)

When using this product

• do not use more than directed

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- symptoms do not get better within 7 days or occur with fever
- 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.** In case of overdose, get medical help or contact a poison control center right away.

Directions

- do not take more than 6 doses in 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 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 20 mg
- store between 15-30°C(59-86°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

citric acid anhydrous, edetate disodium, FD&C blue 1, FD&C red 40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

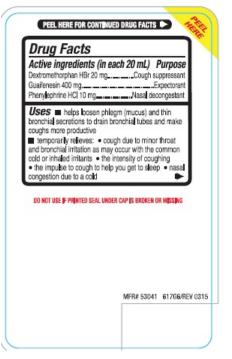
Principal Display Panel

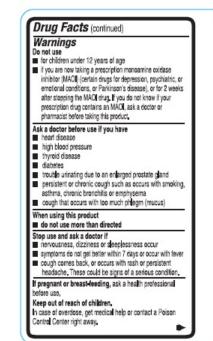
compare to Mucinex Fast-Max Severe Congestion and Cough active ingredients Maximum Strength severe congestion and cough relief Dextromethorphan HBr 20 mg - cough suppressant Guaifenesin 400 mg - expectorant Phenylephrine HCl 10 mg - nasal decongestant Relieves nasal and chest congestion, Soothes cough, Thins and loosens mucus

for ages 12 plus

6 fl oz (177 mL)







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Other inform each 20 mL contai store between 15-3 do not refrigerate dosing cup provided	ation ns: sodium 20 mg 0°C (59-86°F)
edetate disodium, Fl lavors, glycerin, pro	cedients citric acid anhydrous, D&C blue #1, FD&C red #40, pylene glycol, propyl gallate, m benzoate, sodium citrate, anthan gum.

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Ρ	roduct Infor	mation						
P	roduct Type		HUMAN OTC DRUG	Item C	ode (S	iource)	NDC:21	130-817
R	oute of Admini	stration	ORAL					
A	ctive Ingredi	ent/Active	Moiety					
		Ingred	lient Name			Basis of Str	ength	Strengt
	EXTROMETHORPH EXTROMETHORPHA		ROMIDE (UNII: 9D2RTI9KY 3ROTS)	Ή)		DEXTROMETHORP HYDROBROMIDE	HAN	20 mg in 20 mL
Gl	JAIFENESIN (UNII	: 495W7451VQ)	(GUAIFENESIN - UNII:495)	W7451VQ)		GUAIFENESIN		400 mg in 20 mL
	HENYLEPHRINE H III:1WS297W6MV)	YDROCHLORI	DE (UNII: 04JA59TNSJ) (PH	ENYLEPHR		PHENYLEPHRINE HYDROCHLORIDE		10 mg in 20 mL
In	active Ingre	dients						
			Ingredient Name				St	rength
A١	IHYDROUS CITRI	C ACID (UNII: >	(F417D3PSL)					
EDETATE DISODIUM (UNII: 7FLD91C86K)								
	&C BLUE NO. 1							
	26 RED NO. 40		YXOA)					
	YCERIN (UNII: PD							
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)								
PROPYL GALLATE (UNII: 8D4SNN7V92)								
	ATER (UNII: 059Q							
	DIUM BENZOAT	-						
			ILR)					
	DRBITOL (UNII: 50							
	JCRALOSE (UNII: 9							
XA	INTHAN GUM (UN	III: TTV12P4NEE)					
P	roduct Chara	cteristics						
Co	olor	blue (blue co	lored clear liquid)			Score		
	nape		• *			Size		
			Imprint Cod	е				
	ontains							
	ackaging							
P	ltem Code	Pa	ckage Description		Mar	ceting Start Date		eting End Date
Pa #								

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part341	11/11/2015					

Labeler - Safeway (009137209)

Revised: 1/2022

Safeway