# ADULT SEVERE CONGESTION AND COUGH - dextromethorphan hbr, guaifenes in, phenylephrine hcl liquid Mckesson

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.

-----

#### adult severe congestion and cough multi-symptom

#### Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg Guaifenesin 400 mg Phenylephrine HCl 10 mg

#### **Purpose**

Cough suppressant

Expectorant

Nasal decongestant

#### Uses

- hepls 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 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

- 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 coup 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 and C blue 1, FD and 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

adult severe congestion and cough

multi-symptom

Relieves nasal and chest congestion,

Soothes Cough,

Thins and loosens mucus

**DEXTROMETHORPHAN HBr** 

Cough suppressant

**GUAIFENESIN** 

Expectorent

#### PHENYLEPHRINE HCl

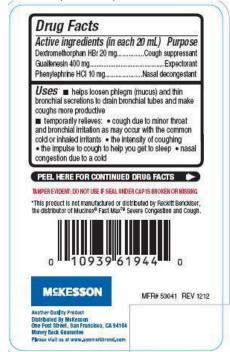
Nasal decongestant,

For Ages 12 and Over

#### **MAXIMUM STRENGTH**



6 fl oz (177 mL)



#### Drug Facts (continued) Warnings Do not use ■ for children under 12 years of age ■ if you are now taking a prescription monoamine oxidase inhibitor (MACI) (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 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 philegm (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 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 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away

#### Drug Facts (continued)

#### Directions

- do not take more than 6 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 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 benzoale, sodium citrate, sorbitol, sucralose, xanthan

## ADULT SEVERE CONGESTION AND COUGH

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-083
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (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
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients	
Ingredient Name	Strength
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8 D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	blue (blue colored clear liquid)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:49348-083-36	177 mL in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	12/01/2012		

# Labeler - Mckesson (177667227)

Revised: 6/2013 Mckesson