CHEST CONGESTION AND COUGH HBP- dextromethorphan hydrobromide, guaifenes in capsule, liquid filled PuraCap Pharmaceutical 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.

Chest Congestion & Cough

Active ingredient (in each softgel)

Dextromethorphan hydrobromide 10 mg Guaifenesin 200 mg

Purpose

Cough suppressant

Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

Do not use 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

- cough that occurs with excessive phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if cough lasts more than 7 days, reoccurs, or occurs with fever, 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. **Abuse of this product can lead to serious injury.**

Directions

- do not exceed recommended dose
- adults and children 12 years and over:

1 or 2 softgels every 4 hours, not more than 12 softgels in 24 hours

• children under 12 years of age: ask a doctor

Other information

- store at room temperature 15-30°C (59-86°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

FD&C Red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white ink

Questions or comments

Call toll free: 1-855-215-8180

Principal Display Panel

CVS Chest Congestion & Cough HBP 20 SOFTGELS

NDC: 51013-406-08

*Compare to the active ingredients in Coricidin® HBP Chest Congestion & Cough



CHEST CONGESTION AND COUGH HBP

dextromethorphan hydrobromide, guaifenesin capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-406
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DEXTROMETHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients	
Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE (UNII: FZ989 GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	red (Clear)	Score	no score
Shape	capsule (Oblong)	Size	21mm
Flavor		Imprint Code	PC37
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:51013-406-08	2 in 1 CARTON	04/06/2017	
1	10 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	04/06/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment			
Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(51013-406), analysis(51013-406)

Revised: 1/2020 PuraCap Pharmaceutical LLC