EXPECTORANT PLUS COUGH RELIEF - guaifenes in and dextromethorphan granule Capricorn Pharma Inc.

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.

Drug Facts

Active Ingredients (in each packet)

Dextromethorphan HBr 5mg Guaifenesin 100mg

Purpose

Cough Suppressant

Expectorant

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus 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

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

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

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

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

- empty entire contents of packet onto tongue and swallow with a glass of water
- for best taste, do not chew granules
- do not take more than 6 doses in any 24-hour period

Age	Dose
adults and children 12 years and over	2 to 4 packets every 4 hours
children 6 years to under 12 years	1 to 2 packets every 4 hours
children 4 years to under 6 years	1 packet every 4 hours
children under 4 years	do not use

Other information

- store between 20-25°C (68-77°F).
- tamper evident: do not use if carton is open or if packets are torn or open.
- see below for lot number and expiration date

Inactive Ingredients

cocoa butter, confectioners sugar, crospovidone, lactose, maltodextrin, methacrylic acid copolymer, microcrystalline cellulose, modified cornstarch, flavor, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, silicon dioxide, sodium lauryl sulfate, sorbitan monostearate, starch, sucralose, sugar, talc, triethyl citrate

Principal Display Panel

Capricorn Pharma
ORIGINAL DEVELOPERS AND MANUFACTURERS

Compare to the active ingredients of Mucinex Cough Mini-Melts

FOR KIDS For ages 4-12

Expectorant plus Cough Relief

DEXTROMETHORPHAN HBr 5mg - Cough Suppressant GUAIFENESIN 100mg - Expectorant

Relieves Chest Congestion Thins and loosens mucus Controls cough Great taste, Easy to Take

FLASHBEADS

12 Packets

Orange Flavor



EXPECTORANT PLUS COUGH RELIEF

guaifenesin and dextromethorphan granule

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66007-204	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg		

Product Characteristics			
Color	white (White to off-white)	Score	
Shape		Size	

Flavor	ORANGE		Imprint Code			
Contains						
Packaging						
# Item Code	Package Description	Marketin	g Start Date	Ma	rketing End D	ate
1 NDC:66007-204-01	12 in 1 CARTON					
Marketing Information						
Marketing Category	Application Number or Monograph Citation		Marketing Start Date		Marketing End	l Date
OTC monograph final	part341		08/06/2010			

Labeler - Capricorn Pharma Inc. (041704524)

Registrant - Capricorn Pharma Inc. (041704524)

Establishment				
Name	Address	ID/FEI	Business Operations	
Capricorn Pharma Inc.		041704524	manufacture	

Revised: 8/2010 Capricorn Pharma Inc.