

MAXIMUM STRENGTH-COUGH AND CHEST CONGESTION DM- maximum strength-cough and chest congestion dm capsule, liquid filled
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.

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-Cough and Chest Congestion DM Liquid Filled Capsules

Drug Facts

Active ingredient (in each softgel)

Dextromethorphan HBr, USP 10 mg

Guaifenesin, USP 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 drain bronchial tubes

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

Stop use and ask a doctor if

cough lasts for more than 7 days, comes back, or is accompanied by 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.

Directions

- do not take more than 12 softgels in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	2 softgels every 4 hours
children under 12 years	do not use

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 special and white edible ink

Manufactured by:

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.

Wuhan, Hubei

430206, China

PRINCIPAL DISPLAY PANEL - Shipping Label

Maximum Strength-Cough and Chest Congestion DM Liquid Filled Capsules

Quantity : 4000 Capsules

NDC. No : 53345-034-01

IMPORTANT:

Inspect immediately upon receipt.

This is a bulk shipment, intended for further processing only.

Protect from heat, humidity, and light. Do not refrigerate.

Store at 15-30°C (59-86°F)

CAUTION : FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

No. 99, 2nd Shendun Road, East Lake New Technology Development District,
Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-034-01

Product:

**Maximum Strength-Cough & Chest
Congestion DM Liquid Filled Capsules**

Each softgel contains: Dextromethorphan HBr 10mg,
Guaifenesin 200mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

40-00029

Quantity:

4000 Capsules

Lot Number:

XXXXXXXX

Manufacturing Date:

xx/yyyy

Box No.:

IMPORTANT:

1. Inspect immediately upon receipt.
2. This is a bulk shipment, intended for further processing only.
3. Protect from heat, humidity, and light. Do not refrigerate.
4. Store at 15-30 °C (59-86 °F)

MADE IN CHINA

REV-01

06/2015

MAXIMUM STRENGTH-COUGH AND CHEST CONGESTION DM

maximum strength-cough and chest congestion dm capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:53345-034

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - 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)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0K00R)	

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE (OBLONG)	Size	18mm
Flavor		Imprint Code	PC37
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-034-01	1 in 1 BOX	06/30/2015	
1		4000 in 1 BAG; 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	06/30/2015	

Labeler - Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd. (421293287)**Establishment**

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	MANUFACTURE(53345-034) , ANALYSIS(53345-034)