

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

**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: 9D2RT19KYH) (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 Drug	M012	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)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.