

**DEXTROMETHORPHAN HBR 15 MG- dextromethorphan hbr capsule, liquid filled**

**Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.**

-----  
**Dextromethorphan HBr Capsules 15 mg, liquid filled**

**Active ingredient (in each softgel)**

Dextromethorphan HBr, USP 15 mg

**Purpose**

Cough suppressant

**Use**

temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold

**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 the user has**

- a cough that occurs with too much phlegm (mucus)
- a cough that lasts or is chronic as occurs with smoking, asthma, 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 8 capsules in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

adults and children 12 years of age and	take 2 capsules every 6 to 8 hours, as
---	--

over	needed
children under 12 years of age	do not use

**Other information**

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- protect from light

**Inactive ingredients**

FD&C blue #1, 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) Ltd.

Wuhan, Hubei

430206, China

**Questions or comments?**

Call toll free 1-855-215-8180

**PRINCIPAL DISPLAY PANEL - Shipping Label**

Dextromethorphan HBr Capsules, 15 mg

Quantity : 12000 Capsules

NDC No. : 53345-011-01

IMPORTANT:

Inspect immediate upon receipt.

This is a bulk shipment intended for further processing only.

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

CAUTION : "FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING"

# Humanwell PuraCap Pharmaceutical (Wuhan) Ltd.

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

NDC No.: 53345-011-01

Product:

## Dextromethorphan HBr Capsules, 15 mg

Each softgel contains: Dextromethorphan HBr USP, 15 mg

**CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING**

Product Code: <b>40-00008</b>	Quantity: <b>12000 Capsules</b>
Lot No.: <b>xxxxxxx</b>	Manufacturing Date: <b>xx/yyyy</b>
Box No.:	<b>IMPORTANT:</b> 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.
<b>MADE IN CHINA</b>	

REV - 00  
04/2013

### DEXTROMETHORPHAN HBR 15 MG

dextromethorphan hbr capsule, liquid filled

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-011
Route of Administration	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

#### Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	red (CLEAR)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (OVAL)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	PC6
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-011-01	1 in 1 BOX	01/30/2014	
1		12000 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	01/30/2014	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-011)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.