

**DEXTROMETHORPHAN HBR 15 MG- dextromethorphan hbr capsule, liquid filled**  
**Humanwell PuraCap Pharmaceutical (Wuhan), 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.*

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**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 over	take 2 capsules every 6 to 8 hours, as 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: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

#### Inactive Ingredients

Ingredient Name	Strength
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<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: HBR47K3TBD)	
<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: 059QF0K00R)	
<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 final	part341	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) , ANALYSIS(53345-011)

Revised: 11/2019

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.