

**DEXTROMETHORPHAN HBR 15 MG- dextromethorphan hbr 15 mg capsule,
liquid filled
AMZ789 LLC**

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.

DEXTROMETHORPHAN HBR 15 MG

Dextromethorphan HBr, USP 15 mg

Cough suppressant

Use

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

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.

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.

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

store at 20-25°C (68-77°F)

avoid excessive heat above 40°C (104°F)

protect from light

FD&C blue #1, FD&C Red #40, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol special, and white edible ink

RxZell[®]NDC 73629-005-10
Compare to Robitussin[®]
Long-Acting CoughGels[®]
active ingredient+**Long Lasting
COUGH RELIEF****Dextromethorphan HBr 15mg**Relieves cough for up to 8 hours
Non-drowsy / non-narcotic**DEXTROMETHORPHAN HBR 15 MG**

dextromethorphan hbr 15 mg capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73629-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
GELATIN (UNII: 2G86QN327L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	

POVIDONE (UNII: FZ989GH94E)

SORBITOL (UNII: 506T60A25R)

Product Characteristics

Color	red (CLEAR)	Score	score with uneven pieces
Shape	OVAL (CAPSULE)	Size	10mm
Flavor		Imprint Code	PC6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73629-005-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2022	

Labeler - AMZ789 LLC (117410213)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell Puracap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(73629-005)

Revised: 5/2022

AMZ789 LLC