

**DAYTIME COLD AND FLU- acetaminophen and dextromethorphan  
hydrobromide capsule, liquid filled  
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd**

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**Daytime Cold and Flu Capsules (PE free)**

***Drug Facts***

**Active Ingredients (in each softgel)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

**Purpose**

Pain Reliever/Fever Reducer

Cough Suppressant

**Uses**

Temporarily relieves common cold/flu symptoms:

- cough due to minor throat and bronchial irritation
- sore throat
- headache
- minor aches and pains
- fever

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 doses in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy alert**

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away

## **Sore throat warning**

If sore throat is severe, lasts for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

## **Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

## **Ask a doctor before use if you have**

- liver disease
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough as occurs with smoking, asthma, or emphysema

## **When using this product do not exceed recommended dose.**

## **Stop use and ask a doctor if**

- pain or cough gets worse or lasts more than 5 days (children) or 7 days (adults)
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts.

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.**

## **Overdose warning**

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## **Directions**

- Take only as directed (see overdose warning)
- Do not take more than 4 doses in 24 hours.

adults and children 12 years and over	2 softgels with water every 4 hours
children 4 to under 12 years	consult a doctor

children under 4 years

do not use

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### **Other information**

- Store at 15° - 30 °C (59°- 86 °F)
- Read all product information before using.
- Tamper evident: Do not use if carton is open or blister unit is broken.

### **Inactive ingredients**

FD&C Red # 40, FD&C Yellow # 6, Gelatin, Glycerin, Polyethylene Glycol 400, Povidone K12, Propylene Glycol, Purified water, Sorbitol Sorbitan Solution, White ink.

### **QUESTIONS OR COMMENTS?**

Call toll free: **1-855-215-8180**

### **PRINCIPAL DISPLAY PANEL**

Daytime Cold and Flu Capsules (PE free)

Each softgel contains: Acetaminophen 325mg/ Dextromethorphan HBr 10mg

NDC 53345-056-01

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.: 53345-056-01**

Product:

**Daytime Cold and Flu Capsules(PE free)**

Each softgel contains: Acetaminophen 325 mg/Dextromethorphan HBr 10 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code:

40-00045

Quantity:

4000 Capsules

Lot Number:

XXXXXXX

Manufacturing Date:

YYYY/MM

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-00  
2025/02

001

**DAYTIME COLD AND FLU**

acetaminophen and dextromethorphan hydrobromide capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53345-056
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN TYPE B BOVINE (150 BLOOM) (UNII: F5AJW0ONK4)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
POVIDONE K12 (UNII: 333AG72FWJ)	
SORBITAN (UNII: 6O92ICV9RU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

## Product Characteristics

Color	orange (Clear)	Score	no score
Shape	CAPSULE (oblong)	Size	17mm
Flavor		Imprint Code	P41
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-056-01	1 in 1 CARTON	12/28/2025	
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	12/28/2025	

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

## Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(53345-056)

Revised: 12/2025

Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd