

COUGH AND COLD PLUS- acetaminophen, phenylephrine hcl, chlorpheniramine maleate, dextromethorphan hbr capsule, liquid filled Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd

Cough and Cold plus

Active ingredients (in each softgel)

Acetaminophen 325 mg

Chlorpheniramine maleate 2 mg

Dextromethorphan hydrobromide 10 mg

Phenylephrine hydrochloride 5 mg

Purpose

Pain reliever/fever reducer

Antihistamine

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these symptoms due to a cold or flu:
- minor aches and pains
- headache
- nasal and sinus congestion
- cough
- runny nose
- sneezing
- sore throat
- temporarily reduces fever

Warnings

Liver warning

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

- more than 10 softgels 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, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use to sedate children.

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
- in children under 12 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- glaucoma
- cough with excessive phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- may cause marked drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- pain, cough, or nasal congestion gets worse or lasts more than 7 days
- 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.

- nervousness, dizziness, or sleeplessness occurs

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

Directions

- do not take more than the recommended dose
- adults and children 12 years and over: take 2 softgels with water every 4 hours. Do not exceed 10 softgels in 24 hours or as directed by a doctor.
- children under 12 years: do not use

Other information

- Store at room temperature 15°-30°C (59°F-86°F) and avoid excessive heat.

Inactive ingredients

Butylated Hydroxyanisole (BHA), D&C red #33, FD&C blue #1, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, white ink

Questions or comments

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

PRINCIPAL DISPLAY PANEL - Shipping Label

Cough and Cold plus Capsules

Each softgel contains: Acetaminophen 325 mg Phenylephrine HCl 5 mg

Chlorpheniramine Maleate 2 mg Dextromethorphan HBr 10 mg

Quantity: 4000 Capsules

NDC No.:53345-045-01

MADE IN CHINA

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. 4.Store at 15-30°C (59-86)°F

Humanwell Puracap Pharmaceuticals (Wuhan)Co., Ltd

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

NDC No.: 53345-045-01



Product:

Cough and Cold plus Capsules

Each softgel contains: Acetaminophen 325 mg Phenylephrine HCl 5 mg
Chlorpheniramine Maleate 2 mg Dextromethorphan HBr 10 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: 40-00023 Quantity: 4000 Capsules

Lot Number: XXXXXXXX Manufacturing Date: mm/yyyy

Box No.:	IMPORTANT:
	1. Inspect immediately upon receipt.
	2. This is a bulk shipment, intended for further processing only.
MADE IN CHINA	3. Protect from heat, humidity, and light. Do not refrigerate.
	4. Store at 15-30 °C (59-86°F)

REV-00
03/2017

COUGH AND COLD PLUS

acetaminophen, phenylephrine hcl, chlorpheniramine maleate, dextromethorphan hbr capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-045
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	PHENYLEPHRINE	5 mg

UNII:1WS297W6MV)	HYDROCHLORIDE	5 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	purple (Clear)	Score	no score
Shape	CAPSULE (Oblong)	Size	21mm
Flavor		Imprint Code	P18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-045-01	1 in 1 BOX	03/24/2017	
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	03/24/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.		421293287	manufacture(53345-045)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd