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

40-00023 4000 Capsules

Lot Number: Manufacturing Date:

xxxxxxx mm/yyyy

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)

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

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td>ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)</td>
<td>ACETAMINOPHEN</td>
<td>325 mg</td>
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<tr>
<td>PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)</td>
<td>PHENYLEPHRINE HYDROCHLORIDE</td>
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<td>CHLORPHENIRAMINE MALEATE (UNII: V1Q009JO9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)</td>
<td>CHLORPHENIRAMINE MALEATE</td>
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<td>DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTF9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)</td>
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Inactive Ingredients
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<tr>
<th>Ingredient Name</th>
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<td>BUTYLATED HYDROXYANISOLE</td>
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<td>D&amp;C RED NO. 33 (UNII: 9DBA0SB01L)</td>
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<td>FD&amp;C BLUE NO. 1 (UNII: HBR47K3TBD)</td>
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<td>GELATIN (UNII: 2G86QN327L)</td>
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<td>GLYCERIN (UNII: PDC6A3C0OX)</td>
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<td>POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)</td>
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<td>POVIDONE (UNII: FZ989GH94E)</td>
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<td>PROPYLENE GLYCOL (UNII: 6DC9Q167V3)</td>
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<td>SORBITAN (UNII: 6O92ICV9RU)</td>
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<td>SORBITOL (UNII: 506T60A25R)</td>
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<td>WATER (UNII: 059QF0K00R)</td>
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**Product Characteristics**

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**Packaging**

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<td>1 in 1 BOX</td>
<td>03/24/2017</td>
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<td>4000 in 1 BAG; Type 0: Not a Combination Product</td>
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**Marketing Information**

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<td>OTC monograph final</td>
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**Labeler** - Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd (421293287)

**Establishment**

<table>
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<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tr>
<td>Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd.</td>
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<td>421293287</td>
<td>manufacture(53345-045), analysis(53345-045)</td>
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Revised: 3/2017