

**ACETAMINOPHEN (RED)- acetaminophen capsule, liquid filled**  
**Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.**

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**ACETAMINOPHEN CAPSULES 325 mg, liquid filled**

**Drug Facts**

**Active ingredient (in each capsule)**

Acetaminophen 325 mg

**Purpose**

Pain reliever/ fever reducer

**Uses**

- Temporarily relieves minor aches and pains due to :
  - headache
  - muscular aches
  - backache
  - minor pain of arthritis
  - the common cold
  - toothache
  - premenstrual and menstrual cramps
- temporarily reduces fever

**Warnings**

**Liver warning:** This product contains acetaminophen. The maximum daily dose of this product is 10 softgels (3,250 mg) in 24 hours for adults or 5 softgels (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

**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 allergic to acetaminophen or any of the inactive ingredients in this product

**Ask a doctor before use if the user has** liver disease

**Ask a doctor or pharmacist before use if the user is** taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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**

**Taking more than the recommended dose (overdose) may cause liver damage.** 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 directed (see overdose warning)**

Adults and children 12 years and over	<ul style="list-style-type: none"><li>• take 2 softgels every 4 to 6 hours while symptoms last</li><li>• do not take more than 10 softgels in 24 hours</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul>
Children 6-11 years	<ul style="list-style-type: none"><li>• take 1 softgel every 4 to 6 hours while symptoms last</li><li>• do not take more than 5 softgels 24 hours</li><li>• do not use for more than 5 days unless directed by a doctor</li></ul>
children under 6 years	<ul style="list-style-type: none"><li>• ask a doctor</li></ul>

**Other information**

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

**Inactive ingredients**

FD&C red #40, FD&C yellow #6, 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

**PRINCIPAL DISPLAY PANEL - Shipping Label**

ACETAMINOPHEN CAPSULES, 325 mg

Quantity : 5000 Capsules  
NDC. No : 53345-010-01

**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.: 53345-010-01

Product:

## ACETAMINOPHEN CAPSULES, 325 mg

Each softgel contains: Acetaminophen USP, 325 mg

**CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING**

Product Code: 40-00017	Quantity: 5000 Capsules
Lot No.: 0000000	Manufacturing Date: 00/0000
Box No.: X	<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  
03/2013

### ACETAMINOPHEN (RED)

acetaminophen capsule, liquid filled

#### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-010
Route of Administration	ORAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

#### Inactive Ingredients

Ingredient Name	Strength
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<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	red (clear)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (oblong)	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	PC17
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-010-01	1 in 1 BOX	04/15/2013	
1		5000 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	M013	04/15/2013	

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

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-010)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.