

**ACETAMINOPHEN (RED)- acetaminophen capsule, liquid filled**  
**Humanwell PuraCap Pharmaceutical (Wuhan), 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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**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 immediately 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"

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## 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

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NDC No.: 53345-010-01

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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
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	

**Product Characteristics**

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

**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 not final	part343	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) , ANALYSIS(53345-010)

Revised: 11/2019

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.