

**PAIN RELIEF EXTRA STRENGTH- acetaminophen capsule, liquid filled  
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.**

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**Drug Facts**

**Active ingredient (in each capsule)**

Acetaminophen 500 mg

**Purpose**

Pain reliever/ fever reducer

**Uses**

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

**Warnings**

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**Liver warning:** This product contains acetaminophen. The maximum daily dose of this product is 6 softgels (3,000 mg) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 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 have ever had an allergic reaction to this product or any of its ingredients

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

**Ask a doctor or pharmacist before use if you are** taking the blood thinning drug warfarin.

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days
- 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**

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 of age 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 6 softgels in 24 hours unless directed by a doctor</li> <li>• do not take more than 10 days unless directed by doctor</li> </ul>
Children 12 years of age	ask a doctor

**Other information**

- store at room temperature 15°-30°C (59°-86°F)

**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

**ACETAMINOPHEN CAPSULES, 500 mg**

Quantity : 3000 Capsules  
 NDC. No : 53345-019-01

**IMP ORTANT:**

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"**

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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.: 53345-019-02**

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Product:

**Acetaminophen Capsules, 500 mg**

Each softgel contains: Acetaminophen 500 mg

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

Product Code: <b>40-00020</b>	Quantity: <b>2000 Capsules</b>
Lot No.: <b>xxxxxxx</b>	Manufacturing Date: <b>xx/yyyy</b>
Box No.:	<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. 4. Store at 15°-30°C (59°-86°F)
<b>MADE IN CHINA</b>	

REV - 01  
06/2014

**PRINCIPAL DISPLAY PANEL - Shipping Label**

**ACETAMINOPHEN CAPSULES, 500 mg**

Quantity : 3000 Capsules  
NDC. No : 53345-019-01

**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.: 53345-019-01

Product:

## Acetaminophen Capsules, 500 mg

Each softgel contains: Acetaminophen USP, 500 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: 40-00020	Quantity: 3000 Capsules
Lot No.: 1000242	Manufacturing Date: 11/2013
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  
11/2013

## PAIN RELIEF EXTRA STRENGTH

acetaminophen capsule, liquid filled

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53345-019
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 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: 059QF0KO0R)	

**SORBITOL** (UNII: 506T60A25R)

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (oblong)	<b>Size</b>	24mm
<b>Flavor</b>		<b>Imprint Code</b>	PC24
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53345-019-01	1 in 1 BOX	01/06/2014	
1		3000 in 1 BAG; Type 0: Not a Combination Product		
2	NDC:53345-019-02	1 in 1 BOX	01/06/2014	
2		2000 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	01/06/2014	

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

**Registrant** - Epic Pharma, LLC (827915443)

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.		421293287	manufacture(53345-019)

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.