

**PAIN RELIEF EXTRA STRENGTH- 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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**Pain Relief Extra Strength capsule, liquid filled**

**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**

**Warnings**

**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 not final	part343	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) , analysis(53345-019)

Revised: 1/2019

Humanwell PuraCap Pharmaceutical (Wuhan), Ltd.