

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

ACETAMINOPHEN CAPSULES 325 mg

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

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.

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 istaking 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

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

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

Questions or Comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL - Shipping Label

ACETAMINOPHEN CAPSULES, 325 mg

Quantity : 4000 Capsules

NDC. No : 53345-010-02

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, 2nd Shendun Road, East Lake New Technology Development District,
Wuhan, Hubei 430206, P. R. China

NDC No.: 53345-010-02

Product:

Acetaminophen Capsules 325 mg

Each softgel contains: Acetaminophen 325 mg

CAUTION: FOR FURTHER MANUFACTURING, PROCESSING OR REPACKAGING

Product Code: 40-00017 Quantity: 4000 Capsules

Lot Number: xxxxxxxx Manufacturing Date: xx/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)
MADE IN CHINA	

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: 059QF0KO0R)	
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:53345-010-02	1 in 1 BOX	04/04/2016	
1		4000 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	04/04/2016	

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

Establishment

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

Revised: 11/2024

Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd