

ACETAMINOPHEN TABLETS, 500 MG EXTRA STRENGTH- acetaminophen tablet
We Care Distributors Inc.

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.

Acetaminophen 500 mg Extra Strength

Important: Read all product information before using. Keep this box for important information.

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Use

- 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

Allergy alert: Acetaminophen may cause severe skin reaction. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Liver warning: This product contains acetaminophen. 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 are allergic to acetaminophen or any of the inactive ingredients in this product

Ask a doctor before use if you have 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

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. (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**
 - take 2 caplets every 6 hours while symptoms last
 - do not take more than 6 caplets in 24 hours, unless directed by a doctor
 - do not use for more than 10 days unless directed by a doctor
- **children under 12 years:** do not use

Other information

- store between 20-25°C (68-77°F)
- **do not use if pouch is torn or open**
- see side panel for lot number and expiration date

Inactive ingredients

hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, polyethylene glycol, polyvinyl pyrrolidone, stearic acid, talc, titanium dioxide

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

PRINCIPAL DISPLAY PANEL - 25 Pouch Box

See New Warnings Information & Directions

**Compare to the Active Ingredients in
Tylenol® Extra Strength ***

**Acetaminophen Tablets, 500 mg
Pain Reliever - Fever Reducer**

NDC: 70005-006-25



EXTRA STRENGTH PAIN RELIEF

COMPARE TO ACTIVE INGREDIENT IN
Tylenol® Extra Strength*

Extra Strength Acetaminophen
For Adults

Pain Reliever/Fever Reducer
Contains no aspirin

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Extra Strength.



25 Pouches of 2 Coated Tablets - 500 mg Each

READ AND KEEP CARTON FOR COMPLETE WARNINGS AND INFORMATION

Drug Facts	
Active Ingredients (in each tablet)	Purposes
Acetaminophen 500 mg	Pain reliever/fever reducer
Uses	
<ul style="list-style-type: none"> ■ temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> ■ headache ■ the common cold ■ backache ■ minor pain of arthritis ■ toothache ■ muscular aches ■ premenstrual and menstrual cramps ■ temporarily reduces fever 	
Warnings	
<p>Allergy alert: Acetaminophen may cause severe skin reaction. Symptoms may include:</p> <ul style="list-style-type: none"> ■ skin redness ■ blisters ■ rash <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> ■ more than 4000 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	
<ul style="list-style-type: none"> ■ 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 <p>Ask a doctor before use if you have liver disease.</p> <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</p>	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ■ 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 <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>Overdose warning: 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.</p>	

Drug Facts (continued)
Directions
<ul style="list-style-type: none"> ■ do not take more than directed (see Overdose warning) ■ adults and children 12 years and over <ul style="list-style-type: none"> ■ take 2 tablets every 6 hours while symptoms last ■ do not take more than 6 tablets in 24 hours ■ do not take for more than 10 days unless directed by a doctor ■ children under 12 years: do not use
Other information
<ul style="list-style-type: none"> ■ store between 20-25°C (68-77°F)
Inactive ingredients
hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, polyethylene glycol, polyvinyl pyrrolidone, stearic acid, talc, titanium dioxide
Questions or comments?
1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Extra Strength.

DO NOT USE IF POUCH IS BROKEN OR TORN



Manufactured For / Distributed by:
We Care Distributor Inc.
Hermitage, TN 37076
www.wecaredistributor.com



ACETAMINOPHEN TABLETS, 500 MG EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-006
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
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	18 mm
Flavor		Imprint Code	BH
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-006-50	50 in 1 BOX		
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-006-25	25 in 1 BOX		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-006-02	2 in 1 POUCH		
3		2 in 1 POUCH; 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	02/08/2016	

Labeler - We Care Distributors Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceutical Ltd.		915664486	manufacture(70005-006)

Revised: 2/2016

We Care Distributors Inc.