## ACETAMINOPHEN- acetaminophen tablet Pharmacy Value Alliance, LLC

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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Extra Strength
Pain Reliever
Acetaminophen Tablets, USP 500 mg (Caplets)
PAIN RELIEVER/FEVER REDUCER
DYE-FREE
For Adults

#### **Active ingredient**

(in each Caplet)

Acetaminophen, USP 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

#### 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

#### 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 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 the reach of children.

#### Overdose warning

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) 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

- 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 ask a doctor

#### Other information

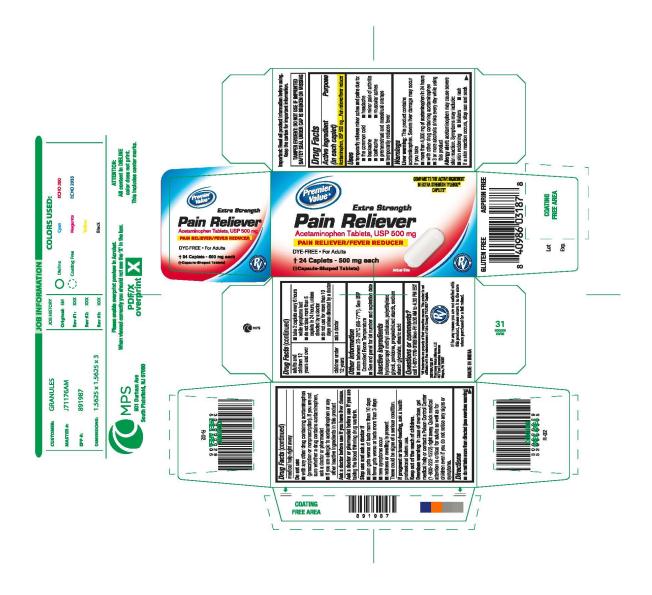
- store between 20-25°C (68-77°F).See USP Controlled Room Temperature
- see end panel for lot number and expiration date

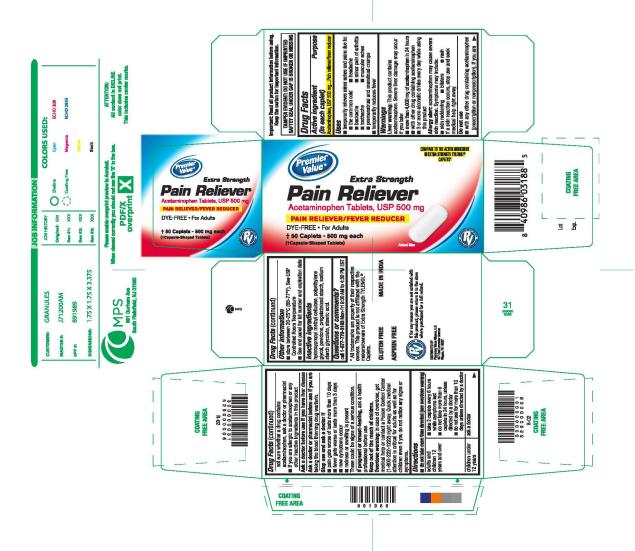
#### **Inactive ingredients**

hydroxypropyl methyl cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

#### Questions or comments?

call 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST.





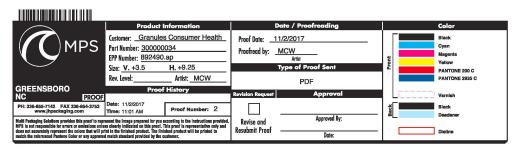


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Route of Administration

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# ACETAMINOPHEN acetaminophen tablet Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-650

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PO VIDO NE (UNII: FZ989 GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	G551	
Contains				

P	Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1	NDC:68016-650-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	0 2/25/20 16			
2	NDC:68016-650-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016			
3	NDC:68016-650-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016			
4	NDC:68016-650-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/25/2016			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part343	02/25/2016				

### Labeler - Pharmacy Value Alliance, LLC (101668460)

Revised: 12/2020 Pharmacy Value Alliance, LLC