

**PAIN RELIEF EXTRA STRENGTH- acetaminophen 500mg capsule, coated**  
**Allegiant Health**

-----  
**426\_328\_012 - Acetaminophen 500mg**

**Active ingredient(s)**

**Acetaminophen 500mg**

**Purpose**

**Pain reliever/fever reducer**

**Use(s)**

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 4,000mg 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

**Pregnancy/Breastfeeding**

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 (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 8 caplets in 24 hours, unless directed by a doctor
- do not take for more than 10 days unless directed by a doctor

**Children under 12 years:** Ask a doctor

**Other information**

- do not use if imprinted safety seal under cap is broken or missing

**Storage**

store between 20°-25°C (68°-77°F)

**Inactive ingredients**

corn starch\*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, purified water\*, sodium starch glycolate, stearic acid, titanium dioxide\*

\*may contain these ingredients

## Questions

Call 1-888-952-0050 Monday to Friday 9am-5pm EST

## Principal Display Panel



<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active ingredient (in each Caplet)</b>	<b>Purpose</b>		
acetaminophen 500 mg	to temporarily relieve pain and reduce fever		
<b>Uses</b>	temporarily relieves minor aches and pains due to:		
	<ul style="list-style-type: none"> <li>■ the common cold</li> <li>■ headache</li> <li>■ backache</li> <li>■ minor pain of arthritis</li> <li>■ toothache</li> <li>■ muscular aches</li> <li>■ premenstrual and menstrual cramps</li> <li>■ temporarily reduces fever</li> </ul>		
<b>Warnings</b>			
	<p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take more than 4,000mg of acetaminophen in 24 hours with other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product.</p> <p><b>Allergy alert:</b> 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.</p> <p><b>Do not use</b> 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> <p><b>Ask a doctor before use if you have liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b></p> <p><b>Stop use and ask a doctor if</b> pain gets worse or lasts more than 10 days or fever gets worse or lasts more than 3 days.</p>		
		<p><b>Directions</b> do not take more than 2 capsules every 6 hours unless directed by a doctor.</p> <p><b>Adults and children 12 years and over</b> take 2 caplets every 6 hours, unless directed by a doctor. Do not take more than 6 caplets in 24 hours unless directed by a doctor.</p> <p><b>Children under 12 years</b> ask a doctor for directions before use.</p>	
		<p><b>Other information</b> Do not use if the seal is broken or missing.</p> <p><b>Inactive ingredients</b> polyethylene glycol, povidone, purified water*, sodium starch glycolate, titanium dioxide* *may contain these ingredients</p>	

## Pain Relief

<b>PAIN RELIEF EXTRA STRENGTH</b>			
acetaminophen 500mg capsule, coated			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69168-426
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
	POVIDONE K30 (UNII: U725QWY32X)		
	POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
	STEARIC ACID (UNII: 4ELV7Z 65AP)		

**SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2)

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
May contain	<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
May contain	<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
May contain	<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	G551
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-426-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/17/2021	
2	NDC:69168-426-40	1 in 1 CARTON	08/05/2021	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69168-426-24	1 in 1 CARTON	12/15/2021	
3		24 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69168-426-32	100 in 1 BOTTLE; Type 0: Not a Combination Product	06/06/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/17/2014	

**Labeler** - Allegiant Health (079501930)

Revised: 5/2021

Allegiant Health