

ACETAMINOPHEN 500MG ES- acetaminophen 500mg tablet

Allegiant Health

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

temporary relief of minor aches and pains associated with

- common cold
- headache
- toothache
- muscular aches
- backache
- arthritis
- menstrual cramps
- temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take

- 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

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

- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription).

If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

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

- symptoms do not improve
- pain gets worse or lasts for more than 10 days
- pain get worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- redness or swelling is present
- a rare sensitivity reaction occurs
- **You may report side effects to 1-888-952-0050**

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children

In case of accidental overdose, contact a doctor or 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 use more than directed (see overdose warning)**
- **adults and children 12 years and over:** take 2 tablets every 4 to 6 hours. Do not take more than 8 tablets in 24 hours.
- **Do not use more than 10 days unless directed by a doctor**
- **children under 12 years of age:** do not use this extra strength product; this will provide more than the recommended dose (overdose) and could cause serious health problems.

Other information

- store between 20°-25°C (68°-77°F)
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

corn starch, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Principal Display Panel

Pain Relief

HealthA2Z[®]
Extra Strength
PAIN RELIEF
Acetaminophen **500 mg**
Pain Reliever-Fever Reducer - CONTAINS NO ASPIRIN
24 Tablets

SEE CARTON FOR COMPLETE INFORMATION

Warnings
Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 4000 mg 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 redness ■ blisters ■ rash

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

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, contact a doctor or Poison Control Center (1-800-222-1222) right away.

Directions

- do not take more than directed (see overdose warning)
- adults and children 12 years and over: take 2 tablets every 6 hours while symptoms last
- do not take more than 8 tablets 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 of age: do not use

Manufactured by:
A Allegiant Health
161672
Deer Park, NY 11729

Lot: _____
Exp: _____

Drug Facts (continued)

Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). ■ 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 ■ dizziness or swelling is present.

These could be signs of a serious condition. ■ You may report side effects to 1-888-952-0090.

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.

Drug Facts (continued)

Directions

■ **Adults and children 12 years and over:** ■ Take 2 tablets every 6 hours while symptoms last.

■ **Do not take more than 8 tablets 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 of age:** ask a doctor.

Other Information ■ Store between 20°-25°C (68°-77°F)

■ Do not use if imprint/safely seal under cap is broken or missing.

Inactive ingredients glycolic acid, stearic acid, croscarmellose sodium, starch, polyethylene glycol, croscarmellose sodium, starch, croscarmellose sodium, starch, croscarmellose sodium, starch.

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 redness ■ blisters ■ rash.

■ A skin reaction occurs, stop use and seek medical help right away.

Uses

Temporarily relieves minor aches and pains due to ■ the common cold ■ headache ■ backache ■ minor pain of arthritis ■ toothache ■ muscular aches ■ menstrual and menstrual cramps ■ temporarily reduces fever.

Active ingredient (in each tablet) Acetaminophen 500mg

Purpose Pain reliever/fever reducer

HealthA2Z® Compare to Tylenol® active ingredient*
 See New Warnings Information **Extra Strength**
PAIN RELIEF
 Acetaminophen **500 mg**
 Pain Reliever-Fever Reducer
 CONTAINS NO ASPIRIN **24 Tablets**

3 69168 01124 3

Lot: Exp:

Drug Facts (continued)

Directions

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Drug Facts (continued)

Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). ■ if you are allergic to acetaminophen or any of the inactive ingredients in this product.

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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 ■ dizziness or swelling is present.

These could be signs of a serious condition. ■ You may report side effects to 1-888-952-0090.

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.

Drug Facts (continued)

Manufactured by:
 Aleant Health
 Deer Park, NY 11729

Lot: 181973
 R0921

*This product is not manufactured or distributed by McNeil Consumer Products Company. Tylenol® is a registered trademark.

ACETAMINOPHEN 500MG ES

acetaminophen 500mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-011
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, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (White)	Score	no score
Shape	ROUND (round)	Size	12mm
Flavor		Imprint Code	AZ;011
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-011-50	1 in 1 CARTON	04/15/2016	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-011-40	1 in 1 CARTON	04/15/2016	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69168-011-24	1 in 1 CARTON	12/15/2021	
3		24 in 1 BOTTLE; 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	04/15/2016	

Labeler - Allegiant Health (079501930)

Revised: 1/2019

Allegiant Health