

PAIN RELIEF EXTRA STRENGTH EXTRA STRENGTH- acetaminophen 500 mg tablet
Allegiant Health

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.

Drug Facts

Active ingredient

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 ■ and reduction of 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 ■ 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

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 ■ fever gets worse or lasts for more than 3 days ■ new symptoms occur ■ redness or swelling is present ■ a rare sensitivity reaction occurs

If you are 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 immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Do not exceed recommended dosage.

Directions

■ **do not use more than directed (see overdose warning)**

■ **adults and children 12 years and over:** take 2 tablets every 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:** do not use this product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage

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 (1-800-222-1222) right away.

Inactive Ingredients

corn starch, hydroxypropyl methylcellulose, polyethylene glycol, pregelatinized starch, stearic acid, titanium dioxide.

May contain povidone, and sodium starch glycolate.

Package/Label Principal Display Panel

Health A2Z®

Compare to Tylenol® active ingredient*

See New Warnings Information

Extra Strength

PAIN RELIEF

500mg

Acetaminophen

Pain Reliever-Fever Reducer

CONTAINS NO ASPIRIN

50 Tablets

LEBG764L2

Drug Facts

Active ingredient (in each tablet) **Purposes**
 Acetaminophen 500 mg Pain reliever/fever reducer

Uses Temporary relief of minor aches and pains associated with: common cold, headache, toothache, muscular aches, backache, arthritis, menstrual cramps, and reduction of 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, or 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.
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.

Drug Facts (Continued)
 See back of package for complete information. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Other information
 Store at controlled room temperature (20°-25°C (68°-77°F)). Do not use if inverted safety seal under cap is broken or missing.

Inactive ingredients
 corn starch, hydroxypropyl methylcellulose, polyethylene glycol, pregelatinized starch, stearic acid, titanium dioxide, and sodium starch glycolate. May contain povidone, and sodium starch glycolate.

*This product is not manufactured or distributed by Acetaminophen, a division of the registered trademark Tylenol®.

LEB0005
R0715

Drug Facts (Continued)

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, fever gets worse or lasts for more than 3 days, new symptoms occur, redness or swelling is present, or 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 immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. **Do not exceed recommended dosage.**

Directions
 do not use more than directed (see overdose warning).
 adults and children 12 years and over: take 2 tablets every 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: do not use this product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.
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 (1-800-222-1222) right away.

50 Tablets

Acetaminophen
Pain Reliever-Fever Reducer

500 mg

PAIN RELIEF

Extra Strength

Compare to Tylenol® active ingredient*
See New Warnings Information

HealthA2Z®

50 Tablets

Acetaminophen
Pain Reliever-Fever Reducer

500 mg


PAIN RELIEF

Extra Strength

Compare to Tylenol® active ingredient*
See New Warnings Information

HealthA2Z®

Lot: OMT A
Exp:



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Manufactured by:
 Allergiant Health
 Deer Park, NY 11729

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

USE ONLY IF IMPRINTED SEAL UNDER CAP IS INTACT
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, which is the maximum daily amount 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: rash, redness, blisters.
If a skin reaction occurs, stop use and seek medical help right away.
 Do not use if you are allergic to acetaminophen or with other products containing acetaminophen.
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 accidental overdose, contact a doctor or Poison Control Center immediately.

Directions
 Do not use more than directed (see overdose warning), adults and children 12 years and over: take 2 tablets every 6 hours. Do not take more than 8 tablets in 24 hours. Do not use more than 10 days unless directed by a doctor.
 In children under 12 years: do not use this product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.

Manufactured by:
Allegiant Health
 Deer Park, NY 11729

LB0204
 R0715

Lot:
Exp:

Label 235

PAIN RELIEF EXTRA STRENGTH EXTRA STRENGTH

acetaminophen 500 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-235
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	AZ235
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-235-05	50 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 NOT FINAL	part343	12/17/2014	

Labeler - Allegiant Health (079501930)

Revised: 12/2015

Allegiant Health