

ACETAMINOPHEN- acetaminophen tablet
Granules USA, Inc

EXTRA STRENGTH

Pain Relief

Acetaminophen USP,500 mg

Pain Reliever/Fever Reducer

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. Prompt 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

■ avoid high humidity

■ 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.



<p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before you start taking the blood thinning drug warfarin.</p> <p>Keep your feet wet as a doctor if</p> <ul style="list-style-type: none">■ your feet get worse or itchy more than 10 days after you start treatment■ your groin area itches more than 5 days after treatment starts■ redness or swelling is present <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health care provider about risks of asthma.</p> <p>Read each warning: In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Drowsiness ■ Do not take more than directed (see overdose warning).</p> <p>Adults and children 12 years and over ■</p> <ul style="list-style-type: none">■ Take 2 capsules every 6 hours while symptoms last.■ Do not take more than 6 capsules in 24 hours, unless directed by a doctor.■ If you miss a dose, skip it; do not urinate directly by a doctor. <p>Elderly and frail patients ■ Ask a doctor.</p>	<p>Other Information</p> <ul style="list-style-type: none">■ Store at 20°–25°C (68°–77°F). See USP Controlled Room Temperature.■ Avoid high humidity.■ Use seal panel for lot number and expiration date. <p>Inactive Ingredients</p> <p>Hypocrotonic acid calcium, povidone iodine, croscarmellose sodium glycol, stearic acid, sodium starch glycolate</p> <p>Questions or comments?</p> <p>Call 1-877-770-3139 Mon-Fri 8:00 AM to 4:30 PM EST</p>
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GRANULES
CONFIDENCE HEALTH

*Compare to the active ingredient in Extra Strength Tylenol® Caplets

EXTRA STRENGTH
Pain Relief
Acetaminophen USP, 500 mg
Pain Reliever, Fever Reducer
FOR ADULTS

actual size

175 Caplets*
(1*Capsule-Shaped Tablets)

Drug Facts

Active Ingredient
(in each Caplet)
Acetaminophen USP 500 mg.....Pain reliever/fever reducer

Purpose

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 drug containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Always alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- blister
- itching
- skin peeling
- itching
- itching

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.

Do not use 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.

Other warnings: (CONTAINED ON BACK OF LABEL)
Keep out of reach of children.
Do not use if you are allergic to any of the ingredients in this product.
Do not use if you are taking other products containing acetaminophen.
Do not use if you are taking other products containing acetaminophen.

Directions: (CONTAINED ON BACK OF LABEL)
Take 2 capsules every 6 hours as needed for pain or fever. Do not take more than 6 capsules in 24 hours.

Other information: (CONTAINED ON BACK OF LABEL)
Keep out of reach of children.
Do not use if you are allergic to any of the ingredients in this product.
Do not use if you are taking other products containing acetaminophen.
Do not use if you are taking other products containing acetaminophen.

Lot: 13874-02030
Exp: 12/2025

Manufactured by:
Confidence Health
35 Westview Blvd., 3rd Floor
Parsippany, NJ 07054

MADE IN INDIA

Unimulated Item

LOT
EXP

6.5 in

9.2 in

0.325 in



ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-003
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)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

STEARIC ACID (UNII: 4ELV7Z65AP)

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	G;551
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-003-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
2	NDC:69848-003-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
3	NDC:69848-003-17	175 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/01/2019	

Labeler - Granules USA, Inc (137098864)

Revised: 8/2023

Granules USA, Inc