

ACETAMINOPHEN- acetaminophen tablet
Granules Pharmaceuticals Inc.

Acetaminophen Tablets 500 mg

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 24 hours.
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday 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 drugs 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 other 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 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 reach of children

Over dose warning: In case of overdose, get medical help or Contact Poison Control Center right away. (1-800-222-1222) 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • ask a doctor

OTHER INFORMATION

- store at 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

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

QUESTIONS OR COMMENTS ?

Contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

+All trademarks are property of their respective owners.

This product is not affiliated with the makers/owners of Extra Strength Tylenol[®] Caplets.

Distributed by:

Granules Pharmaceuticals INC.,

Chantilly, VA 20151

MADE IN INDIA

Rev.08/21

PRINCIPAL DISPLAY PANEL

NDC 70010-161-01

**EXTRA STRENGTH
Acetaminophen
Tablets USP**
500 mg
**Pain Reliever/Fever Reducer
FOR ADULTS**

actual size


100 Caplets*
(capsule-shaped tablets)

Keep carton for complete product information.
TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet)
Acetaminophen, USP 500 mg.....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 drug containing acetaminophen
- 3 or more alcoholic drinks every day while using this product.

Allergy alert: acetaminophen may cause severe skin reaction. 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

(CONTINUED ON BACK OF LABEL)
Distributed by:
Granules Pharmaceuticals Inc., 2020000357
Chantilly, VA 20151 7000000321

Rev.08/21 Contains No Aspirin MADE IN INDIA

LOT EXP
LL0067-00

 RECYCLE

To simulate a printed label, fold along dotted line.

Inside (adhesive side)

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

- 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 right away. (1-800-222-1222) 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	<ul style="list-style-type: none"> ■ 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 methylcellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Questions or comments?
call 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST

NDC 70010-161-01
*Compare to the Active Ingredients
of Extra Strength Tylenol® Caplets

EXTRA STRENGTH Acetaminophen Tablets USP

500 mg

Pain Reliever/Fever Reducer
FOR ADULTS

100 Caplets*
(*capsule-shaped tablets)



NDC 70010-161-01

EXTRA STRENGTH Acetaminophen Tablets USP

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*Compare to the Active Ingredients
of Extra Strength Tylenol® Caplets

EXTRA STRENGTH Acetaminophen Tablets USP

500 mg

Pain Reliever/Fever Reducer
FOR ADULTS



Lot
Exp.

Drug Facts (continued) Keep out of the reach of children. These could be harmful if used as directed. If present at onset-feeding, ask a health professional before use.	
Warnings: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-235-7225). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.	
Directions	Other information
<ul style="list-style-type: none"> do not take more than directed (see overdose warning) adults and children 12 years and over <ul style="list-style-type: none"> take 2 caplets every 6 hours while symptoms last do not take more than 6 caplets in 24 hours do not use for more than 10 days unless directed by a doctor ask a doctor 	<ul style="list-style-type: none"> store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. avoid high humidity. See and read label for lot number and expiration date.
<ul style="list-style-type: none"> children under 12 years 	Inactive ingredients
	hydroxypropyl methylcellulose, hydroxypropyl cellulose, pregelatinized starch, sodium starch glycolate, croscarmellose sodium
	Questions or comments?
	*All trademarks are property of their respective owners. The package is registered with the trademark owner of Extra Strength Tylenol® Caplets.

Contains No Aspirin
Row-08221
MADE IN INDIA
Granules Pharmaceuticals Inc.,
Chandley, VA, 20151

Important: Read all product information before using. Keep the caplet in its original container.	Warnings: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-235-7225). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.
Drug Facts	Other information
<ul style="list-style-type: none"> temporarily relieves minor aches and pains due to: <ul style="list-style-type: none"> backache muscle aches premenstrual and menstrual cramps temporary headache do not take more than directed (see overdose warning) adults and children 12 years and over <ul style="list-style-type: none"> take 2 caplets every 6 hours while symptoms last do not take more than 6 caplets in 24 hours do not use for more than 10 days unless directed by a doctor ask a doctor 	<ul style="list-style-type: none"> store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature. avoid high humidity. See and read label for lot number and expiration date.
Active ingredient (in each caplet): Acetaminophen, USP, 500 mg	Inactive ingredients
	hydroxypropyl methylcellulose, hydroxypropyl cellulose, pregelatinized starch, sodium starch glycolate, croscarmellose sodium
Uses	Questions or comments?
	*All trademarks are property of their respective owners. The package is registered with the trademark owner of Extra Strength Tylenol® Caplets.

0022-001

STARCH, CORN (UNII: O8232NY3SJ)

STEARIC ACID (UNII: 4ELV7Z65AP)

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

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)

POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)

Product Characteristics

Color	white (White to off-White)	Score	no score
Shape	CAPSULE (Caplet shape)	Size	17mm
Flavor		Imprint Code	G551
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70010-161-01	1 in 1 CARTON	02/15/2022	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:70010-161-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2022	
3	NDC:70010-161-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	02/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/15/2022	

Labeler - Granules Pharmaceuticals Inc. (079825711)

Registrant - Granules India Limited (918609236)

Revised: 4/2025

Granules Pharmaceuticals Inc.