

**ACETAMINOPHEN- acetaminophen tablet
Granules USA, Inc**

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.

**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.

code # :
 size : 1+3/4 X 1+3/4 X 3+3/8
 ref # : RP2180404B view : 12
 material : 016 858 date : 12

COATING FREE AREA

R-00
537000012



3000004 15

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

24 Caplets†
 (Orange-Striped Tablets)

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

24 Caplets†
 (Orange-Striped Tablets)

extra size



8 13874 02023 0

Lot
Exp.

COATING FREE AREA

COATING FREE AREA

R-00
537000012



3000004 15

33

Drug Facts (continued)

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 seek 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)

<p>adults and children 12 years and over</p>	<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
<p>children under 12 years</p>	<ul style="list-style-type: none"> ■ ask a doctor

Drug Facts (continued)

Other Information

■ store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature

■ See and pay attention to lot number and expiration date

■ avoid high humidity

Inactive Ingredients

hydroxypropyl methyl cellulose, pregelatinized starch, polydioxanone, polyethylene glycol, stearic acid, sodium starch glycolate

Questions or comments?

call 1-877-776-3183 Mon-Fri 9:00 AM to 4:30 PM EST

*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 Consumer Health
 35 Hudson New Blvd., 3rd Floor
 Parsippany, NJ 07054

MADE IN INDIA

Important: Read all product information before using. Keep the carton for important information.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient	Purpose
Acetaminophen, USP 500 mg	Pain reliever/fever reducer

Uses

- temporarily relieve minor aches and pains due to:
 - the common cold
 - headache
 - toothache
 - minor pain of arthritis
 - muscular aches
 - premenstrual and menstrual cramps
 - temporarily reduce 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 check 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

- with any other drug containing acetaminophen (prescription or nonprescription), if you are

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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†
(†Capsule-Shaped Tablets)

Important: Read all product information before using.
WARNING: OVERDOSE: DO NOT TAKE IF IMPRINTED SAFETY SEAL UNDER CAP OR 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:
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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 take acetaminophen when you have severe skin rash or if you experience any of the following symptoms:

- stomach pain or upset
- loss of appetite
- nausea or vomiting
- dark urine
- itching
- yellowing of the skin or eyes

Do not use with any other drug containing acetaminophen. If you take more than 4,000 mg of acetaminophen, if you experience any of the symptoms listed above, or if you have a severe skin rash or any of the symptoms listed above, stop taking this product and call your doctor right away.

Ask a doctor before use if you have liver disease

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 capsule every 6 hours with or without food. Do not take more than 8 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.

LOT: 8-13874-02030

EXP: 8

UNIMPRINTED AREA

Distributed by: Emerald Commerce Health
 25 Westview Blvd., 3rd Floor
 Pennsylvania, PA 19104
 MADE IN INDIA

6.5 in

2.25 in

end user :	GRANTISS
item :	CVS APAP RR 100CT
code # :	
size :	2-1/3/32 X 2-1/3/32 X 4-1/3/16
ref # :	PPI180618A view
material :	016 838 date



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 not final	part343	07/01/2019	

Labeler - Granules USA, Inc (137098864)

Revised: 1/2023

Granules USA, Inc