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. Promt 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

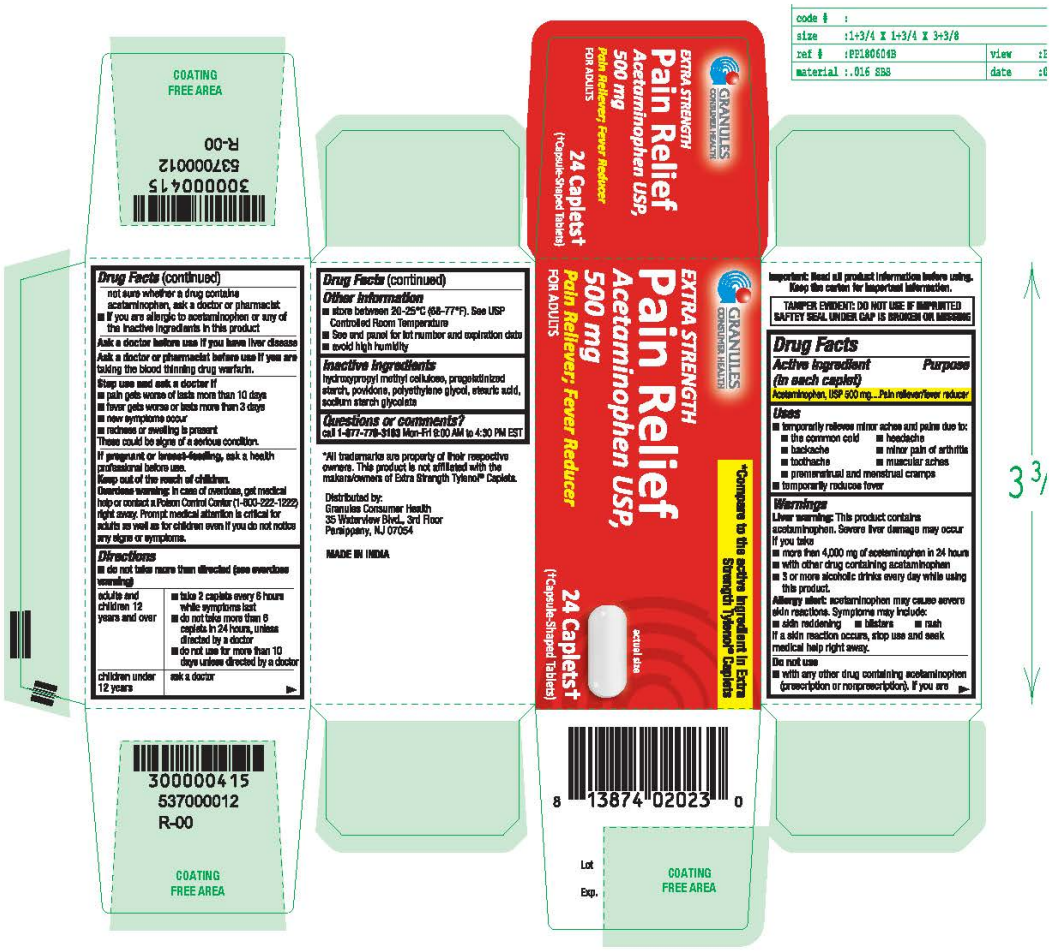
■ see end panel for lot number and expiration date

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.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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 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.
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Drug Facts (continued)
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Questions or comments?
call 1-877-778-9183 Mon-Fri 8:00 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 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054
MADE IN INDIA
EXTRA STRENGTH
Pain Relief
Acetaminophen USP, 500 mg
Pain Reliever; Fever Reducer
FOR ADULTS
24 Caplets†
(†Capsule-Shaped Tablets)
GRANULES CONSUMER HEALTH
*Compares to the active ingredient in Extra Strength Tylenol® Caplets
actual size
8 13874 02023 0
Lot
Exp.
COATING FREE AREA
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 (in each caplet) Purpose
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 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
3 3/4

E 1

6.5 in

2.25 in

GRANULES
CONSUMER 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.

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

Drug Facts

Active ingredient (in each caplet)	Purpose
Acetaminophen, USP 500 mg	Pain reliever/fever reducer

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- skin reddening
- blisters
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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)

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Distributed by:
Granules Consumer Health
35 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

MADE IN INDIA

8 13874 02030 8

LOT

EXP

Unvarnished Area

GS

.92"

.325"

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 (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.

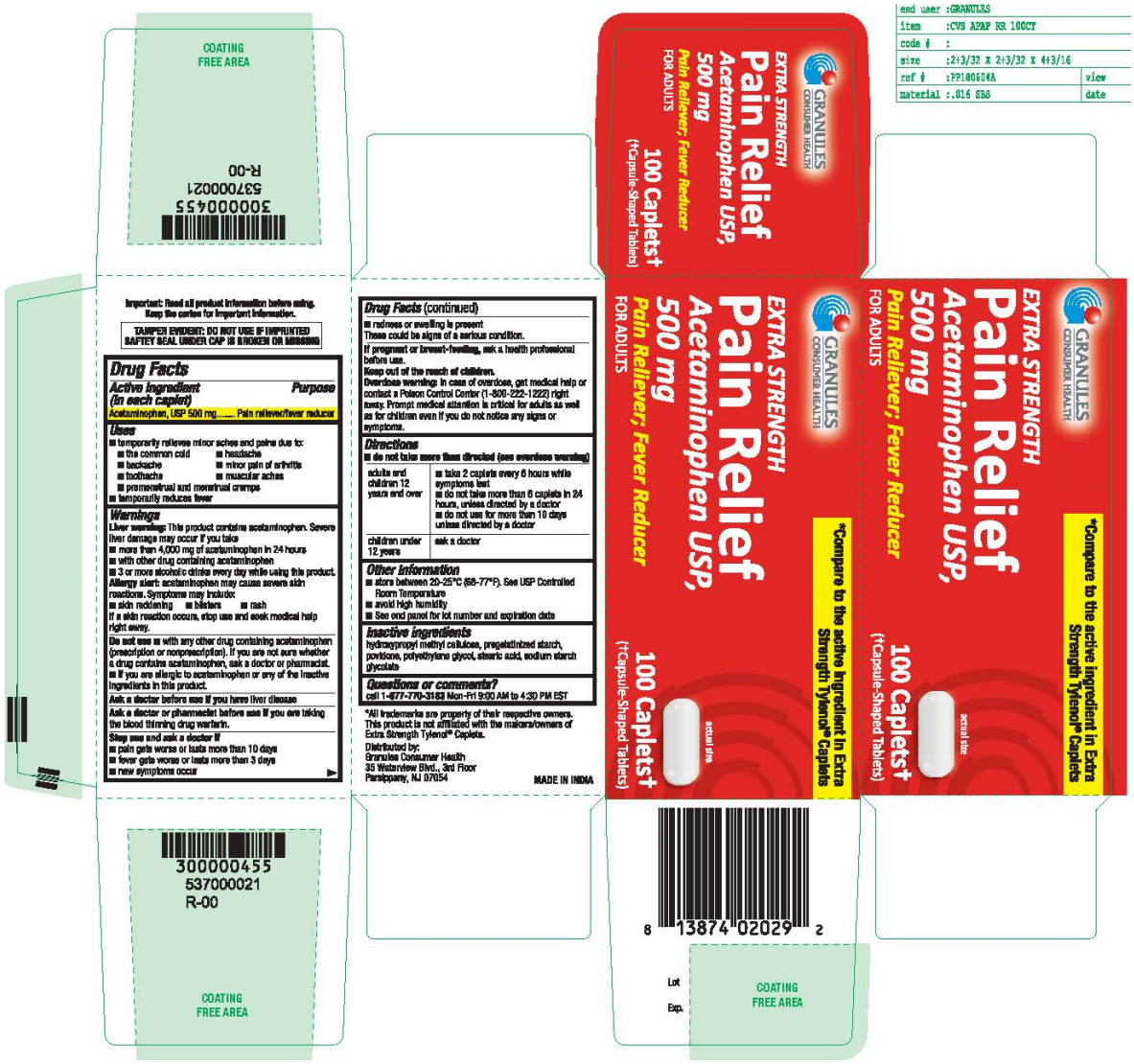
Directions
- do not take more than directed (see overdose warning)

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

Questions or comments?
call 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST



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: 3WQ0SDW1A)	

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: 12/2024 Granules USA, Inc