

ACETAMINOPHEN- acetaminophen tablet
Trifecta Pharmaceuticals USA LLC

Acetaminophen 500mg

Active Ingredient (in each caplet)

Acetaminophen USP, 500mg

Purpose

Pain Reliever / Fever Reducer

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.

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 relieves fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4000mg 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

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.

Keep out of reach of children

Keep out of reach of children

Directions

Do not take more than directed. See overdose warning

Adults and children 12 years and older

- Take 2 tablets every 6 hours while symptoms last
- Do not take more than 6 tablets 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 of age

- Ask a doctor

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 a sign of a serious condition

If pregnant or breast-feeding

Ask a health professional before use

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 children even if you do not notice symptoms.

Other Information

- Store at 20°C - 25°C (68°F - 77°F). See USP controlled room temperature
- Avoid high humidity
- See end panel for expiration date and lot number
- Tamper Evident. Do not use if imprinted safety seal under cap is broken or missing
- Important. Read the directions and warnings before use

Inactive Ingredients

hydroxypropyl methyl cellulose, polyethylene glycol, povidone K-30, Pregelatinized starch, Sodium starch glycolate, Stearic Acid

Questions or Comments?

Call 1-888-296-9067

Distributed By:

Distributed By:

Trifecta Pharmaceuticals USA®

Ft. Lauderdale, FL. 33301 USA


1-888-296-9067

*This product is not manufactured or distributed by the Johnson & Johnson Corporation, owner of the registered trademark Tylenol®

Made in the USA

Package Label

OUTSIDE LABEL



Compare to the active ingredient in Extra Strength Tylenol® Caplets

NDC: 69396-144-01


EXTRA-STRENGTH

Acetaminophen

Caplets, 500mg

Pain Reliever / Fever Reducer for Adults

Aspirin Free



Actual Size

For the Temporary Relief of Minor Aches and Pains

1,000 CAPLETS
500mg each

DRUG FACTS

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

Uses
Temporarily relieves minor aches and pains due to:
• colds and flu
• headache
• menstrual and muscular cramps
• temporarily reduces fever

Warnings
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
• more than the recommended dose
• 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 redness • blisters • rash
If a skin reaction occurs, stop use and seek medical help right away.

Directions
With any other drug containing acetaminophen (by 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

Stop use and ask a doctor if
• you experience any of the following symptoms:
• fever gets worse or lasts more than 3 days
• redness or swelling is present
These could be a sign of a serious condition.

Keep out of reach of children. See important information about safety for children on page 2 of this Medication Guide.
Keep out of reach of children. See important information about safety for children on page 2 of this Medication Guide.

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 symptoms.

Directions
• **do not take more than directed (see overdose warning)**
• 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° to 25° (68° to 77° F). See USP controlled room temperature.
• Avoid high humidity.
• See and patient for expiration date and lot number.

Inactive ingredients
Croscarmellose, Cellulose, Polyethylene glycol, Povidone K-30, Pregelaminized starch, Sodium starch glycolate, Stearic acid

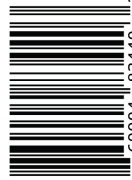
Questions or comments? Call 1-888-236-9007

DO NOT USE WITH OTHER MEDICATIONS CONTAINING ACETAMINOPHEN

*This product is not manufactured or distributed by the Johnson & Johnson Corporation, owner of the registered trademark "Tylenol".

Important: READ THE DIRECTIONS AND WARNINGS BEFORE USE

KEEP EVIDENCE: DO NOT USE IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



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MADE IN THE USA

Distributed by:
Trifecta Pharmaceuticals USA*
FL Lauderdale, FL 33301 USA
1-888-236-9007

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-144
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
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

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:69396-144-01	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/07/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/08/2023	

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 11/2023

Trifecta Pharmaceuticals USA LLC