

ACETAMINOPHEN- acetaminophen caplet, 500 mg extra strength tablet
HealthRight Products, LLC

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.

Acetaminophen 500 mg Extra Strength

Important: Read all product information before using. Keep this box for important information.

Drug Facts

Active ingredient (in each caplet)

Acetaminophen USP 500 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to

- headache
- tooth pain
- backache
- PMS and menstrual cramps
- temporarily reduces fever
- minor arthritis
- the common cold
- muscular pain

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: more than 6 tablets in 24 hours, which is the maximum daily amount

- with other drugs 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.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

Stop use and ask a doctor if

- You are suffering from any liver disease
- you are taking the blood thinning drug warfarin
- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Dosage

Adults and children over 12 years of age, Take 2 caplets every 6 hours while symptoms last, do not take more than 6 caplets in 24 hours, unless directed by a doctor.

☐ **Children under 12**, ask a doctor.

Storage

- Store in a cool and dry place
- Store between 22-25°C (67-77°F)

Inactive ingredients

Micro crystalline Cellulose, Corn Starch, Sodium Starch Glycolate Type A, Sodium Lauryl sulfate, Sodium Methyl Paraben, Magnesium Stearate, Talc, Croscarmellose Sodium and polyvinyl pyrrolidone K-30

Information

Tamper Evident: Do not use if safety seal under cap is broken or missing

☐ **Swallow whole, do not crush, chew, split or dissolve**

PRINCIPAL DISPLAY PANEL - 200 CT

Acetaminophen Caplet, 500 mg

Pain Reliever - Fever Reducer

Active ingredient (in each caplet) **Purpose**
Acetaminophen USP 500mgPain reliever/fever reducer

Uses: temporarily relieves minor pains and aches due to:

- headache
- minor arthritis
- tooth pain
- the common cold
- backache
- muscular pain
- PMS and menstrual cramps
- temporarily reduces fever

Storage:
Store in a cool and dry place
Store between 22 - 25°C (67 - 77°F)

Restorz®
Acetaminophen caplets
Distributed by
HealthRight Products™
info@healthrightproducts.com

For questions or comments,
please call | Para preguntas o
comentarios, for favor llame
877-780-6673

Contains no aspirin

DRUG FACTS

Warnings:
Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take more than 6 tablets in 24 hours, which is the maximum daily amount. • with other drugs containing acetaminophen • 3 or more alcoholic drinks every day while using this product.

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Information
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Code No.: HP/DRUGS/09/92 Batch No.:
Mfg. Date: Exp. Date:

ACETAMINOPHEN			
acetaminophen caplet, 500 mg extra strength tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77800-100
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	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
STARCH, CORN (UNII: O8232NY3SJ)			
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)			
SODIUM LAURYL SULFATE (UNII: 368GB5141J)			
METHYL PARABEN SODIUM (UNII: CR6K9C2NHK)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
TALC (UNII: 7SEV7J4R1U)			
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
POVIDONE K30 (UNII: U725QWY32X)			
Product Characteristics			
Color	white (White to Off-White)	Score	2 pieces
Shape	CAPSULE (Caplet Shape)	Size	18 mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77800-100-01	200 in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	07/24/2020	

Labeler - HealthRight Products, LLC (831577916)

Revised: 7/2020

HealthRight Products, LLC