ACETAMINOPHEN- acetaminophen tablet, film coated Walgreens Co.

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

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 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 have ever had an allergic reaction to this product or any of its ingredients.

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 reach of children.

OVERDOSE WARNING

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

Directions

Do not take more than directed.

SEE OVERDOSE WARNING.

adults & children 12 years of age and over	 take 2 caplets every 6 hours while symptoms last do not take more than 6 caplets in 24 hours, unless directed by doctor do not take more than 10 days, unless directed by a doctor
children under 12 years of age	• ask a doctor

Other information

- store at room temperature between 20-25° C (68-77° F)
- avoid excessive heat, cold and humidity
- close cap tightly after use

Inactive ingredients

hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

Questions or comments?

call 1 (888) 577-8033

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015

PRINCIPAL DISPLAY PANEL - 30 Caplet Bottle Carton

BONUS SIZE | 24 + 6 FREE NDC 0363-0143-03

Walgreens

Compare to Tylenol® Extra Strength Caplets active ingredient^{††}

Pain Reliever ACETAMINOPHEN 500 mg / PAIN RELIEVER / FEVER REDUCER EXTRA STRENGTH CAPLETS

30 CAPLETS

ACTUAL SIZE



ACETAMINOPHEN

acetaminophen tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0143
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients		
Ingredient Name	Strength	
hypromellose, unspecified (UNII: 3NXW29V3WO)		
magnesium stearate (UNII: 70097M6I30)		
microcrystalline cellulose (UNII: OP1R32D61U)		
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)		
povidone, unspecified (UNII: FZ 989GH94E)		
stearic acid (UNII: 4ELV7Z65AP)		
talc (UNII: 7SEV7J4R1U)		
titanium dioxide (UNII: 15FIX9V2JP)		

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	S500	
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0363-0143- 03	1 in 1 CARTON	04/01/2020		
1		30 in 1 BOTTLE; Type 0: Not a Combination Product			
2	NDC:0363-0143- 06	1 in 1 CARTON	04/01/2020		
2		60 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part343	04/01/2020		

Labeler - Walgreens Co. (008965063)

Revised: 5/2022 Walgreens Co.