

**ACETAMINOPHEN- acetaminophen tablet
WALGREEN CO.**

**Rapid Release Gelcaps
EXTRA STRENGTH
Acetaminophen Gelcaps USP, 500 mg
Pain reliever; Fever reducer
Aspirin free**

Active ingredient (in each Gelcap)

Acetaminophen, USP 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- headache
- muscular aches
- backache
- minor pain of arthritis
- toothache
- the common cold
- premenstrual and menstrual cramps
- temporarily reduces fever

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 the reach of children.

In case of accidental 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.

Overdose warning

In case of accidental 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 signs or symptoms.

Directions

■ do not take more than directed (see overdose warning)

adults and children 12 years and over

- take 2 gelcaps every 6 hours while symptoms last
- do not take more than 6 gelcaps in 24 hours, unless directed by a doctor
- do not take 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

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, croscarmellose sodium, D&C red #33, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hypromellose, iron oxide red, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone, pregelatinized starch, propylene glycol, shellac glaze, stearic acid, titanium dioxide, yellow iron Oxide.

Questions or comments ?

call **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

PDP



ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-9798
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
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

GELATIN (UNII: 2G86QN327L)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
AMMONIA (UNII: 5138Q19F1X)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	gray (Encapsulated with red opaque and blue gray opaque hard gelatin shells)	Score	score with uneven pieces
Shape	OVAL	Size	19mm
Flavor		Imprint Code	G1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9798-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2021	
2	NDC:0363-9798-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2021	
3	NDC:0363-9798-15	150 in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2022	
4	NDC:0363-9798-21	225 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2022	
5	NDC:0363-9798-37	375 in 1 BOTTLE; Type 0: Not a Combination Product	06/25/2022	
6	NDC:0363-9798-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	09/24/2021	

Labeler - WALGREEN CO. (008965063)

Revised: 12/2024

WALGREEN CO.