# 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
- he 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 Centerright 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** 



ted label,

Inside (adhesive side)

cell 1-477-470-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST

ark a doctor

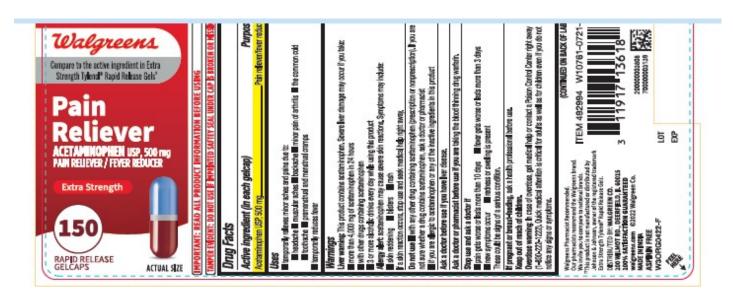
(68"-77"F). See USP Centrolled Room

Temperature

blue #1, FD&C hydroxypropy Like 2 galaxys every 6 hours white symptoms leaf do not take mere than 5 galaxys in 24 hours, unless cinetted by a doctor do not use for more than 10 days unless directed by a

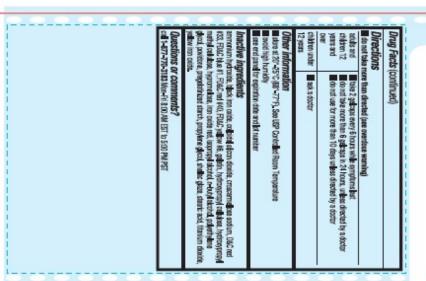
reeding, ask a health prefessional before use, highten, case of everdose, get medical help or carriant a ght away (1–600–222–1222). Oulek medical dulls as well as fer children even if you do not





ed label, Hine.

### Inside (adhesive side)









# **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	<b>Basis of Strength</b>	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	500 mg	

Inactive Ingredients		
Ingredient Name	Strength	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)		
FERROSOFERRIC 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: 46N107B710)
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: FZ 989GH94E)
STARCH, CORN (UNII: O8232NY3SJ)
STEARIC ACID (UNII: 4ELV7Z65AP)
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)
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: 1/2024 WALGREEN CO.