ACETAMINOPHEN- acetaminophen tablet CVS PHARMACY, INC

Extra Strength

Acetaminophen Gelcaps USP, 500mg

Pain reliever/Fever reducer

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
- the common cold
- toothache
- 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 are allergic to acetaminophen or any of the inactive ingredients in this product

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.

Keep out of the reach of children.

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 expiration date and lot number

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.

Principal Display Panel







Inside (adhesive side)

use if you are taking the blood



ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69842-295

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 GELATIN (UNII: 2G86QN327L) STEARIC ACID (UNII: 4ELV7Z65AP) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) FERRIC OXIDE YELLOW (UNII: EX43802MRT) POVIDONE K30 (UNII: U725QWY32X) POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)

SHELLAC (UNII: 46N107B710)
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
STARCH, CORN (UNII: O8232NY3SJ)
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)
ISOPROPYL ALCOHOL (UNII: ND2M416302)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
FD&C RED NO. 40 (UNII: WZB9127XOA)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
FERRIC OXIDE RED (UNII: 1K09F3G675)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
AMMONIA (UNII: 5138Q19F1X)
FERROSOFERRIC OXIDE (UNII: XM0M87F357)
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)

Product Characteristics						
Color	gray (Encapsulated with red opaque and blue gray opaque hard gelatin shells)	Score	no score			
Shape	OVAL	Size	19mm			
Flavor		Imprint Code	G1			
Contains						

ı	Packaging					
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
:	NDC:69842-295- 05	50 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2023			
:	NDC:69842-295- 10	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2023			
3	NDC:69842-295- 15	150 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2023			
	NDC:69842-295- 21	225 in 1 BOTTLE; Type 0: Not a Combination Product	03/03/2023			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC Monograph Drug	M013	03/03/2023			

Labeler - CVS PHARMACY, INC (062312574)

Revised: 11/2024 CVS PHARMACY, INC