

PAIN RELIEF- acetaminophen tablet, coated
AAA Pharmaceutical, Inc.

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.

RES - 1170 - 2022-0922

Drug Facts

Active ingredient (in each gelcap)

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 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 reach of children.

Overdose warning

In case of 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	<ul style="list-style-type: none">▪ 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 use for more than 10 days unless directed by a doctor
children under 12 years	<ul style="list-style-type: none">▪ ask a doctor

Other information

- store between 20-25°C (68-77°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #33, edible ink, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

RESTORE U

NDC 57344-170-01

†COMPARE TO THE ACTIVE INGREDIENT IN TYLENOL® EXTRA STRENGTH RAPID
RELEASE GELS

For Adults

EXTRA STRENGTH

Pain Relief

Acetaminophen

Pain Reliever, Fever Reducer

50 GELCAPS - 500 MG EACH

Actual Size

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING



DO NOT USE IF PRINTED SEAL
UNDER CAP IS BROKEN OR MISSING

F117002RES, 01
This product is not manufactured or distributed by Michael Consumer
Healthcare, distributor of Tylenol Extra Strength Rapid Release Gels.

NC

Drug Facts

Active ingredient (in each gelcap) **Purpose**
Acetaminophen 500 mg...Pain reliever/fever reducer

Uses

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

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
- skin 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.

Drug Facts (continued)

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 (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	<ul style="list-style-type: none"> 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 use for more than 10 days unless directed by a doctor
children under 12 years	<ul style="list-style-type: none"> ask a doctor

Other information

- store between 20-25°C (68-77°F)
- retain carton for complete product information

Drug Facts (continued)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, D&C red #33, edible ink, FD&C blue #1, FD&C red #40, FD&C yellow #6, gelatin, hydroxypropyl cellulose, hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?
1-844-705-4384

Distributed by:
AAA Pharmaceutical, Inc.
661 Main Street
Lumberton, NJ 08048
Made in India



PAIN RELIEF			
acetaminophen tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-170
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

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)
D&C RED NO. 33 (UNII: 9DBA0SBB0L)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
GELATIN (UNII: 2G86QN327L)
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)
HYPROMELLOSES (UNII: 3NXW29V3WO)
FERROSO FERRIC OXIDE (UNII: XM0M87F357)
FERRIC OXIDE RED (UNII: 1K09F3G675)
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
POVIDONE (UNII: FZ989GH94E)
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)
STEARIC ACID (UNII: 4ELV7Z65AP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	gray (red and light blue ends)	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	G1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-170-01	1 in 1 CARTON	09/01/2017	09/30/2022
1		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:57344-170-02	1 in 1 CARTON	01/01/2015	
2		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:57344-170-03	1 in 1 CARTON	09/01/2017	10/31/2022
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:57344-170-12	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2017	06/30/2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/01/2015	

Revised: 9/2022

AAA Pharmaceutical, Inc.