

ACETAMINOPHEN- acetaminophen capsule
FFREDS, 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.

EXTRA STRENGTH
PAIN RELIEVER
ACETAMINOPHEN, USP 500 mg

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. The maximum daily dose of this product is 6 gelcaps (3,000 mg) in 24 hours. 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 reaction. 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.**Overdose warning**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. 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 use for more than 10 days unless directed by a doctor

children under 12 years

ask a doctor

Other information

- store between 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, black iron oxide irradiated, colloidal silicon dioxide, croscarmellose sodium, gelatin, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hypromellose, iron oxide red, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone k-30, pregelatinized starch, propylene glycol, shellac glaze (modified), stearic acid, titanium dioxide, yellow iron oxide.

Questions or comments?

call 1-877-770-3183 Mon-Fri 9:00 AM to 4:30 PM EST

**EXTRA STRENGTH
PAIN RELIEVER
ACETAMINOPHEN, USP 500 mg
Pain Reliever/Fever Reducer
24 GELCAPS
500 mg each**

fred's Pharmacy

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Compare to the Active Ingredient in
Extra Strength TYLENOL® Rapid Release Gels*

ACTUAL SIZE



RAPID RELEASE

fred's Pharmacy

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ACTUAL SIZE



RAPID RELEASE

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Drug Facts (continued)

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 got 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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In cases of overdose, get medical help or contact a Poison Control Center (1-800-232-1222) right away. 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)
- take 2 gelcaps every 6 hours while symptoms last
- not take more than 6 gelcaps in 24 hours, unless directed by a doctor
- do not use more than 10 days unless directed by a doctor
- ask a doctor

children under 12 years

Drug Facts (continued)

Other Information

- store between 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, black iron oxide irradiated, colloidal silicon dioxide, croscarmellose sodium, gelatin, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, iron oxide red, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, povidone K-30, pregelatinized starch, propylene glycol, shellac glaze (modified), stearic acid, titanium dioxide, yellow iron oxide

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100% satisfaction guaranteed

Questions or comments:
1-888-331-FRED (3723)

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MEMPHIS, TN 38116
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MADE IN INDIA

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Drug Facts

Important: Read all product information before using. Keep carton for important information.

TYLENOL BRAND: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

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

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
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Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 gelcaps (3,000 mg) in 24 hours. 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 redness
- skin itching
- hives
- swelling of the face, lips, tongue, or throat
- difficulty breathing
- itching, redness, or swelling of the skin
- itching, redness, or swelling of the mouth
- itching, redness, or swelling of the eyes
- itching, redness, or swelling of the hands or feet
- itching, redness, or swelling of the feet
- itching, redness, or swelling of the hands
- itching, redness, or swelling of the face
- itching, redness, or swelling of the tongue
- itching, redness, or swelling of the throat
- itching, redness, or swelling of the chest
- itching, redness, or swelling of the stomach
- itching, redness, or swelling of the intestines
- itching, redness, or swelling of the bladder
- itching, redness, or swelling of the rectum
- itching, redness, or swelling of the vagina
- itching, redness, or swelling of the penis
- itching, redness, or swelling of the testicles
- itching, redness, or swelling of the scrotum
- itching, redness, or swelling of the anus
- itching, redness, or swelling of the perineum
- itching, redness, or swelling of the buttocks
- itching, redness, or swelling of the back
- itching, redness, or swelling of the neck
- itching, redness, or swelling of the head
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- itching, redness, or swelling of the perineum
- itching, redness, or swelling of the buttocks
- itching, redness, or swelling of the back
- itching, redness, or swelling of the neck
- itching, redness, or swelling of the head

Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains

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ACETAMINOPHEN

acetaminophen capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-987
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
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMMONIA (UNII: 5138Q19F1X)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
GELATIN (UNII: 2G86QN327L)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
SHELLAC (UNII: 46N107B71O)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	gray (one red opaque and one blue-gray hard gelatin shells)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	G1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-987-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/17/2017	

Labeler - FFREDS, INC (005866116)

Revised: 7/2017

FFREDS, INC