

ACETAMINOPHEN- acetaminophen capsule
FREDS, 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
Pain Reliever/Fever Reducer

Active ingredient

(in each Caplet)
Acetaminophen, USP 500 mg

Purpose

Pain reliever/fever reducer

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

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 other 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

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

- take 2 caplets every 6 hours while symptoms last
- do not take more than 6 caplets 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
- See end panel for lot number and expiration date

Inactive ingredients

hydroxypropyl methyl cellulose, pregelatinized starch, povidone k-30, polyethylene glycol, stearic acid, sodium starch glycolate

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

100 CAPLETS**

**** Capsule-Shaped Tablets**

500 mg each



EXTRA STRENGTH PAIN RELIEVER

ACETAMINOPHEN, USP 500 mg

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500 mg each

Pain Reliever/Fever Reducer

*Compare to the Active Ingredient in
Extra Strength Tylenol® Caplets

ACTUAL
SIZE



Lot
Exp.

COATING FREE AREA



Drug Facts (continued)

Other information

- store between 20°-25°C (68°-77°F). See USP Controlled Room Temperature.
- see end panel for lot number and expiration date

Inactive ingredients

- hydroxypropyl methyl cellulose, pregelatinized starch, polydona k-30, polyethylene glycol, stearic acid, sodium starch glycolate

Questions or comments?

call 1-877-776-3183 Mon-Fri 9:00 AM to 4:30 PM EST
*All trademarks are property of their respective owners. This product is not affiliated with the makers/owners of Extra Strength TYLENOL® Caplets

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www.fredsinc.com
MADE IN INDIA

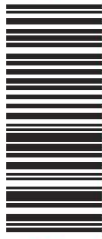


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COATING FREE AREA

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Drug Facts (continued)

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: 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
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children under 12 years



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COATING FREE AREA

COATING FREE AREA



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EXTRA STRENGTH
PAIN RELIEVER
ACETAMINOPHEN, USP 500 mg
Pain Reliever/Fever Reducer
500 CAPLETS
500 mg each



*Compare to Active Ingredient in Extra Strength Tylenol® Caplets

PAIN RELIEVER

ACETAMINOPHEN, USP 500 mg

Pain Reliever/Fever Reducer

EXTRA STRENGTH

FOR ADULTS



ACTUAL SIZE

500 CAPLETS
500 mg each

Important: Read all product information before using.

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet)
Acetaminophen, USP 500 mg

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
- menstrual 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 drug 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

Do not use
if a skin reaction occurs, stop use and seek medical help right away.

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
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If pregnant or breast-feeding, ask a health professional before use.

(CONTINUED ON BACK OF LABEL)

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Questions or comments:



Exp: 53100000 R-00
Lot: 845791272



Drug Facts (continued)

Keep out of the reach of children.

Overdose warning: 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

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Inactive ingredients

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Questions or comments?

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ACETAMINOPHEN

acetaminophen capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-989
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
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	G551
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-989-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/17/2017	
2	NDC:55315-989-50	500 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 - FREDS, INC (005866116)