

ACETAMINOPHEN- acetaminophen tablet
Safetec of America, 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.

Drug Facts

Active ingredients (in each caplet)

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 last 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

- 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 the product at controlled room temperature 15°-30°C (59°-86°F).
- Protect from light, moisture and freezing.

Inactive ingredients

hypromellose, polyethylene glycol, povidone k30, pregelatinized starch, sodium starch glycolate, stearic acid.

Questions or comments?

Call toll free: **1-800-456-7077**

Principal Display Panel – Pouch Label

DO NOT USE IF POUCH IS TORN OR DAMAGED

Safetec

of America, Inc.

Manufactured for Safetec of America, Inc.

Buffalo NY 14215

Acetaminophen 500 mg

Pain Reliever/Fever Reducer



DO NOT USE IF POUCH IS TORN OR DAMAGED
Manufactured for Safetec of America, Inc.
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Acetaminophen 500 mg Pain Reliever/Fever Reducer

Drug Facts EXTRA STRENGTH 2 Caplets

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 ■ toothache ■ muscular aches ■ premenstrual and menstrual cramps
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Warnings
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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

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 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.

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ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 10 10-440 6
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
hypromellose 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	
povidone k30 (UNII: U725QWY32X)	
starch, corn (UNII: O8232NY3SJ)	
sodium starch glycolate type a potato (UNII: 5856J3G2A2)	
stearic acid (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	17mm
Flavor		Imprint Code	500
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 10 10-4406-0	2 in 1 POUCH; Type 0: Not a Combination Product	12/30/2019	
2	NDC:6 10 10-4406-1	50 in 1 BOX	12/30/2019	
2	NDC:6 10 10-4406-0	2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:6 10 10-4406-2	100 in 1 BOX	12/30/2019	
3	NDC:6 10 10-4406-0	2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/30/2019	

Labeler - Safetec of America, Inc. (874965262)

Revised: 12/2019

Safetec of America, Inc.