

ACETAMINOPHEN- acetaminophen tablet
Strive Pharmaceuticals 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.

Acetaminophen 500mg

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hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

- do not take more than directed.SEE OVERDOSE WARNING

adults and children 12 years of age 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 of age ask a doctor

*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 4000mg 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 non prescription). 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 a 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. Prompt medical attention is critical for adults as well as children even if do not notice any signs or symptoms.

Keep out of reach of children

Overdose Warning: In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Pain reliever / Fever reducer

- store at room temperature between 20 °C - 25 °C (68 °F - 77 °F)
- avoid excessive heat, cold and humidity
- close cap tightly after use

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-399
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
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TALC (UNII: 7SEV7J4R1U)	
STARCH, CORN (UNII: O8232NY3S)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	BH
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-399-06	60 in 1 PACKAGE; Type 0: Not a Combination Product	08/03/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	08/03/2020	

Labeler - Strive Pharmaceuticals Inc. (080028013)

