

ACETAMINOPHEN 500MG- acetaminophen 500mg 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

Acetaminophen 500mg

colloidal silicon dioxide, gelatin, glycerin, hydroxypropyl methyl cellulose, maize starch, magnesium stearate, purified talc, sodium starch glycolate

- take with a full glass of water
- do not take more than directed

adults and children 12 years of age and over	<ul style="list-style-type: none">• 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 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.

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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)

†Compare to active ingredient in
TYLENOL Extra Strength
RIGHT REMEDIES
Pain Relief
+ pain reliever/fever reducer
EXTRA STRENGTH
acetaminophen **500mg** each caplet **60** caplets
NDC 70692-117-06

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION. CAMPER EVIDENT. Do not use if immediate safety seal under cap is broken or missing.

Drug Facts

Active Ingredient (in each tablet) Purpose
Acetaminophen 500mg 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.

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 reach of children.**

Directions: Do not take more than directed. 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 take for more than 10 days unless directed by a doctor. Children under 12 years: ■ ask a doctor.

Other information: ■ store at room temperature between 20° - 25° C (68° - 77° F) ■ avoid excessive heat, cold and humidity.

Questions or comments? Call 1 (888) 577-8033.

Distributed by: STRIVE PHARMACEUTICALS, INC.
East Brunswick, NJ 08816 LB70692C11706-1 REV. 11/2016

Lot No. _____
Exp. Date _____



†compare to active ingredient in
TYLENOL® Extra Strength Caplets

NDC 70692-117-06

Pain Relief

⊕ pain reliever/fever reducer
EXTRA STRENGTH

acetaminophen
500mg each caplet



60
caplets



Pain Relief

⊕ pain reliever/
fever reducer
acetaminophen 500mg

**READ AND KEEP OUTER PACKAGE FOR
COMPLETE PRODUCT INFORMATION**

†This product is not manufactured or distributed by
Johnson & Johnson Consumer Inc., McNeil Consumer
Healthcare Division, owner of the registered
trademark Tylenol® Extra Strength Caplets.



†compare to active ingredient in
TYLENOL® Extra Strength Caplets

NDC 70692-117-06

Pain Relief

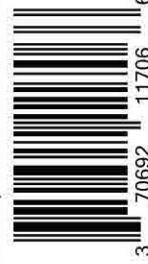
⊕ pain reliever/fever reducer
EXTRA STRENGTH

acetaminophen
500mg each caplet



60
caplets

Distributed by: STRIVE PHARMACEUTICALS INC.
East Brunswick, NJ 08816 - CT11706 - REV.00-072019



3 70692 11706 6

**COATING
FREE AREA**

Lot. No.:

Exp. Date:

Drug Facts (continued)
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 you do not notice any signs or symptoms.

Directions
Do not take more than directed. **SEE OVERDOSE WARNING.**
adults & children
12 years of age and over
children under 12 years of age
■ take 2 caplets every 6 hours while symptoms last
■ do not take more than 6 caplets in 24 hours, unless directed by doctor
■ do not take more than 10 days, unless directed by a doctor
■ ask a doctor

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

Inactive ingredients
carnauba wax, calcium silicate dihydrate, gelatin, glycerine, hydroxypropyl methyl cellulose, hypromellose, magnesium stearate, maize starch, mineral oil, polyethylene glycol, pregelatinized starch, purified talc, purified water, sodium carboxymethyl cellulose, sodium starch glycolate, stearic acid, titanium dioxide. * may contain one or more of these ingredients.

Questions or comments?
Call 1 (888) 577-8033

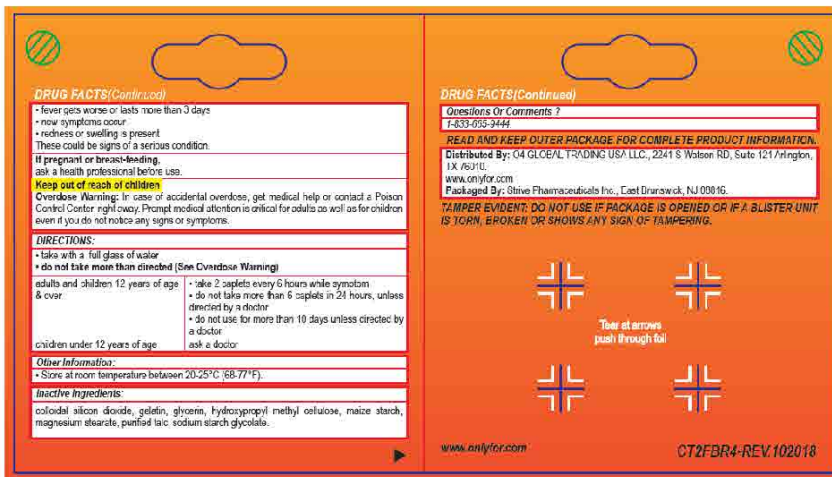
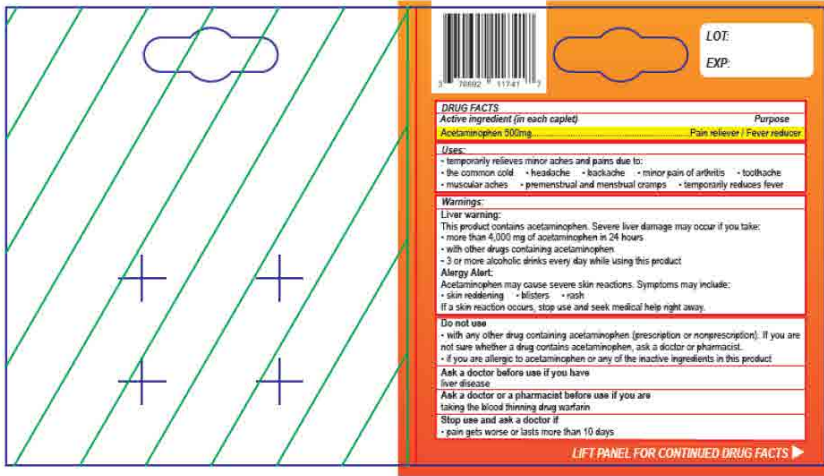
Drug Facts
Active Ingredient (in each caplet)
Acetaminophen 500mg. **Pain reliever/fever reducer.**

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 drugs containing acetaminophen
Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
■ skin redness ■ 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.



ACETAMINOPHEN 500MG

acetaminophen 500mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70692-117
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)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	18mm
Flavor		Imprint Code	A5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70692-117-41	4 in 1 PACKAGE; Type 0: Not a Combination Product	12/20/2018	
2	NDC:70692-117-06	60 in 1 BOTTLE; Type 0: Not a Combination Product	12/20/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	12/20/2018	

Labeler - Strive Pharmaceuticals Inc (080028013)