

CAREONE ACETAMINOPHEN- acetaminophen tablet
American Sales Company

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.

American Sales Company Acetaminophen Drug Facts

Active ingredient (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 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.

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	<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	ask a doctor

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

carnauba wax, corn starch*, croscarmellose sodium*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid

*may contain one or more of these ingredients

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Extra Strength Tylenol®

Extra Strength

ACETAMINOPHEN 500mg

Actual Size

Pain Reliever/Fever Reducer

For Adults

Gluten Free

OUR PHARMACISTS RECOMMEND

100 CAPLETS



**This product is not manufactured or distributed by Johnson & Johnson Consumer Inc., distributor of Extra Strength Tylenol®.
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 LANDOVER, MD 20785 • 1-877-846-9949
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 Quality guaranteed or your money back.

NDC 41520-064-78
CAREone[®]
 Compare to the active ingredient
 in Extra Strength Tylenol®**
Extra Strength
ACETAMINOPHEN
500mg
 Pain Reliever/Fever Reducer
 For Adults
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100 CAPLETS

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- 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

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Drug Facts (continued)

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Inactive ingredients camellia wax, corn starch*, croscarmellose sodium*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate*, stearyl acid *may contain one or more of these ingredients

Questions or comments? 1-800-719-9260

DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING



LOT NO.

EXP.

: 46478 OF C3

CAREONE ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-064
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE (caplet)	Size	16mm
Flavor		Imprint Code	L484
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-064-71	1 in 1 CARTON	07/20/2016	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41520-064-78	1 in 1 CARTON	07/20/2016	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41520-064-90	1 in 1 CARTON	07/20/2016	
3		500 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:41520-064-76	1 in 1 CARTON	07/20/2016	
4		120 in 1 BOTTLE; 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	07/20/2016	

Labeler - American Sales Company (809183973)

Revised: 12/2018

American Sales Company