CAREONE ACETAMINOPHEN- acetaminophen tablet, film coated 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:
- headache
- muscular aches
- backache
- minor pain of arthritis
- the common cold
- toothache
- 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	 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

croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, mica-based pearlescent pigment, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid

Questions or comments?

1-800-719-9260

Package/Label Principal Display Panel

Compare to the active ingredient in Tylenol® Extra Strength Rapid Release Gels

Extra Strength

ACETAMINOPHEN

500mg

Actual Size

Pain Reliever/Fever Reducer

Rapid Release

For Adults

Gluten Free

OUR PHARMACISTS RECOMMEND

100 CAPLETS



DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING ** This product is not manufactured or distributed Johnson & Johnson Consumer Inc., distributor of Tylenol ® Extra Strength Rapid Release Gels. DISTRIBUTED BY FOODHOLD U.S.A., LLC LANDOVER, MD 20785 · 1-877-846-9949 ©2017 S&S Brands, LLC Quality guaranteed or your money back.

Drug Facts

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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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- 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.

Drug Facts (continued)

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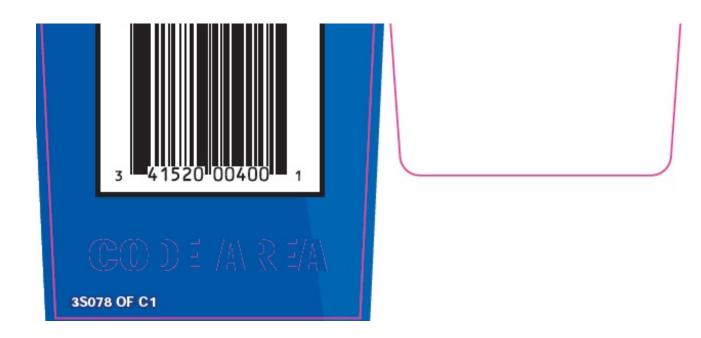
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12 years

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CAREONE ACETAMINOPHEN

acetaminophen tablet, film coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:41520-786

Route of Administration ORAL

Active Ingredient/Active Moiety

I	Ingredient Name	Basis of Strength	Strength
I	ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	500 mg

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
PO VIDO NE (UNII: FZ989 GH9 4E)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		

Product Characteristics				
Color	RED	Score	no score	
Shape	OVAL	Size	18 mm	
Flavor		Imprint Code	3S0	
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:41520-786-78	1 in 1 CARTON	12/21/2017		
1		100 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	12/21/2017		

Labeler - American Sales Company (809183973)

Revised: 12/2019 American Sales Company