

CARE ONE PAIN RELIEF 8 HOUR- acetaminophen tablet, film coated, extended release
American Sales Company

American Sales Company 8 Hour Pain Relief Drug Facts

Active ingredient (in each caplet)

Acetaminophen 650 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
- muscular aches
- backache
- headache
- minor pain of arthritis
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- 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 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 8 hours with water• swallow whole: do not crush, chew, split or dissolve• do not take more than 6 caplets in 24 hours• do not use for more than 10 days unless directed by a doctor
children under 12 years	<ul style="list-style-type: none">• do not use

Other information

- store at 20-25°C (68-77°F). Avoid excessive heat 40°C (104°F).

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Tylenol® 8HR

8 HOUR PAIN RELIEF

Acetaminophen Extended-Release Tablets, 650mg

Pain Reliever/Fever Reducer

Actual Size

For Up to 8 Hour Relief of Minor Muscle Aches and Pain

50 CAPLETS*

650mg EACH

See New Warning

*Capsule-Shaped Tablets

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)			ACETAMINOPHEN	650 mg
Inactive Ingredients				
Ingredient Name			Strength	
CARNAUBA WAX (UNII: R12CBM0EIZ)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
HYPROMELLOSES (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
POVIDONE (UNII: FZ989GH94E)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	RED	Score	no score	
Shape	CAPSULE	Size	19mm	
Flavor		Imprint Code	L217	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-217-71	1 in 1 CARTON	11/29/2005	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41520-217-78	1 in 1 CARTON	11/29/2005	
2		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
ANDA	ANDA075077		11/29/2005	

Labeler - American Sales Company (809183973)