CORE VALUES PAIN RELIEVER- acetaminophen tablet Harmon Stores 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.

Harmon Stores Inc. Pain Reliever 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	 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

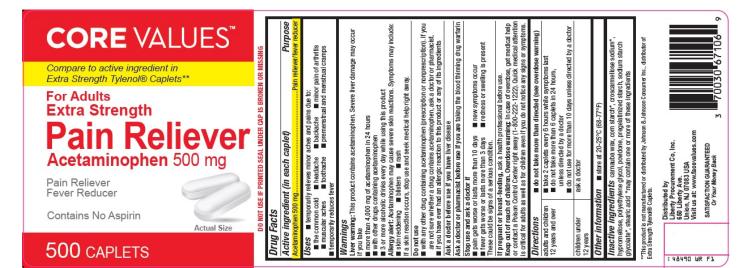
carnauba wax, corn starch*, croscarmellose sodium*, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate*, stearic acid

*may contain one or more of these ingredients

Principal Display Panel

Compare to active ingredient in Extra Strength Tylenol® Caplets

For Adults Extra Strength Pain Reliever Acetaminophen 500 mg Pain Reliever Fever Reducer Contains No Aspirin Actual Size 500 CAPLETS



CORE VALUES PAIN RELIEVER

acetaminophen tablet					
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code (Source	Item Code (Source)		
Route of Administration	ORAL				
Active Ingredient/Active I	Moiety				
	Strength	trength Strength			
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPH					500 mg
Inactive Ingredients					
	St	Strength			
CARNAUBA WAX (UNII: R12CBM)EIZ)				
STARCH, CORN (UNII: 08232NY3	SJ)				
HYPROMELLOSES (UNII: 3NXW2	29V3WO)				
POLYETHYLENE GLYCOL (UNI	I: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)					

STE	EARIC ACID (UNII: 4	4ELV7Z6	5AP)					
CRO	OSCARMELLOSE	SODIUM	(UNII: M28OL1HH	H48)				
-	1	• .•						
Pro	oduct Characte	ristics						
Col	Color WHITE			Score			no score	
Sha	ıpe	OVAL Size			16 mm			
Fla	vor	Imprint Code			L484	L484		
Cor	ntains							
Pa	ckaging							
#	Item Code		Package Description		Marketing Start Dat	te N	Marketing End Date	
1 N	IDC:63940-484-90	500 in 1) in 1 BOTTLE; Type 0: Not a Combination Product		11/26/2018			
M	arketing Info	rmati	ion					
	•							
	larketing Categor		-	eror	Monograph Citation	Marketing Start Da	te I	Marketing End Date
OTO	C monograph not fin	al part3	343			11/26/2018		

Labeler - Harmon Stores Inc. (804085293)

Revised: 11/2018

Harmon Stores Inc.