

## **CETAFEN EXTRA- acetaminophen tablet** **HART Health**

*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.*

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### **CETAFEN EXTRA**

**Active Ingredient** (in each caplet): **Acetaminophen** 500mg

#### **Purpose**

Pain Reliever / Fever Reducer

#### **Uses:**

Temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- backache
- minor arthritis pain
- the common cold
- toothache
- 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
- rash
- blisters

**Do not use** with any other drug containing acetaminophen (prescription or non-prescription)

**Ask a doctor or pharmacist before use if**

- you are taking the blood thinning drug warfarin
- you do not know if other drugs you are taking contain acetaminophen

**Ask a doctor before use if** you have liver disease

**Stop use and ask a doctor if**

- an allergic reaction occurs, seek medical help right away
- new symptoms occur
- redness or swelling is present
- fever worsens or lasts more than 3 days
- pain worsens or lasts more than 10 days

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:** Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. In case of overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222.

**Directions:****Do not take more than directed**

Adults and children 12 years of age and over:

- take 2 caplets every 4 to 6 hours while symptoms persist
- do not take more than 8 caplets in 24 hours unless directed by a doctor

Children under 12 years of age: ask a doctor

**Other information:**

- caplets enclosed in a sealed packet
- do not use if packet is torn, cut or open
- store at 59° to 86°F (15°-30°C)
- avoid excessive heat and humidity

**Inactive Ingredients:** corn starch, hypromellose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide

50 count  
PMS 329C green  
PMS 7404C yellow  
small medication box dieline  
10.8cm x 6cm x 9cm



- KEY**
- cut line \_\_\_\_\_
  - inward fold line - - - - -
  - outward fold line . . . . .
  - perf \_\_\_\_\_
  - slit \_\_\_\_\_
  - outside glue
  - inside glue

## CETAFEN EXTRA

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50332-0149
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	AZ012
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0149-3	20 in 1 BOX, UNIT-DOSE	01/05/1990	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0149-4	50 in 1 BOX, UNIT-DOSE	01/05/1990	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:50332-0149-7	125 in 1 BOX, UNIT-DOSE	01/05/1990	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:50332-0149-8	250 in 1 BOX, UNIT-DOSE	01/05/1990	
4		2 in 1 PACKET; Type 0: Not a Combination Product		
5	NDC:50332-0149-1	400 in 1 BOX, UNIT-DOSE	01/05/1990	
5		2 in 1 PACKET; 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	01/05/1990	

**Labeler** - HART Health (069560969)