

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.

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

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

- more than 8 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

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

- 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

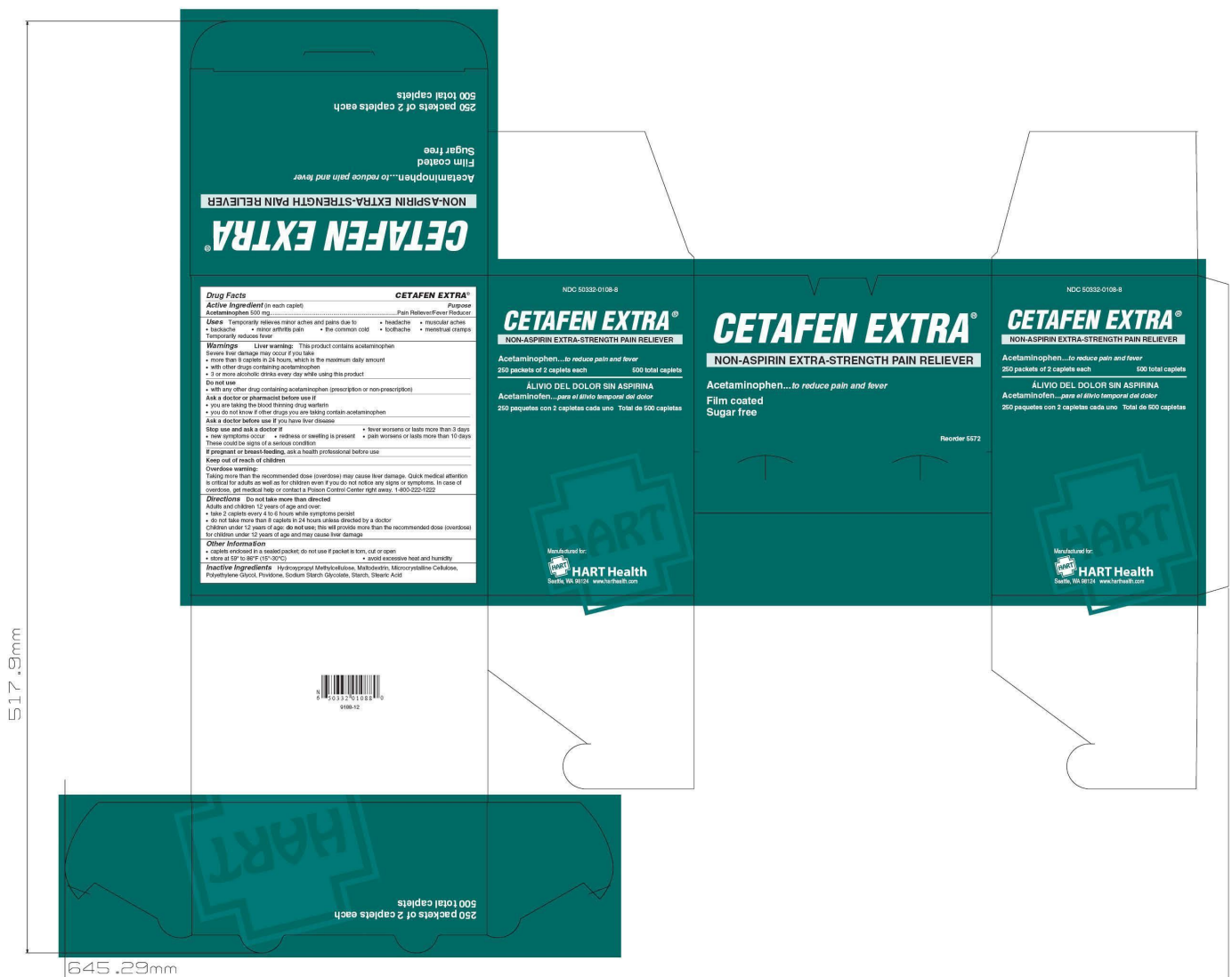
Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. In case of overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222.

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: do not use; this will provide more than the recommended dose (overdose) for children under 12 years of age and may cause liver damage.

Inactive Ingredients: Hydroxypropyl Methylcellulose, Maltodextrin, Microcrystalline Cellulose, Polyethylene Glycol, Povidone, Sodium Starch Glycolate, Starch, Stearic Acid



CETAFEN EXTRA

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0108
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
HYDROXYPROPYL METHYLCELLULOSE E5 [III] (UNII: R75537T0T4)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	CFNX
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0108-3	20 in 1 BOX, UNIT-DOSE		
1		2 in 1 PACKET		
2	NDC:50332-0108-4	50 in 1 BOX, UNIT-DOSE		
2		2 in 1 PACKET		
3	NDC:50332-0108-7	125 in 1 BOX, UNIT-DOSE		
3		2 in 1 PACKET		
4	NDC:50332-0108-8	250 in 1 BOX, UNIT-DOSE		
4		2 in 1 PACKET		
5	NDC:50332-0108-1	400 in 1 BOX, UNIT-DOSE		
5		2 in 1 PACKET		

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)

Revised: 11/2012

HART Health