CETAFEN- 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_{||}

Active Ingredient (in each tablet): Acetaminophen 325mg

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 8 tablets 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 symptom occur
- redness or swelling is present
- fever worsens or lasts for more than 3 days
- pain worsens or lasts for 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 Poison Control Center right away. 1-800-222-1222

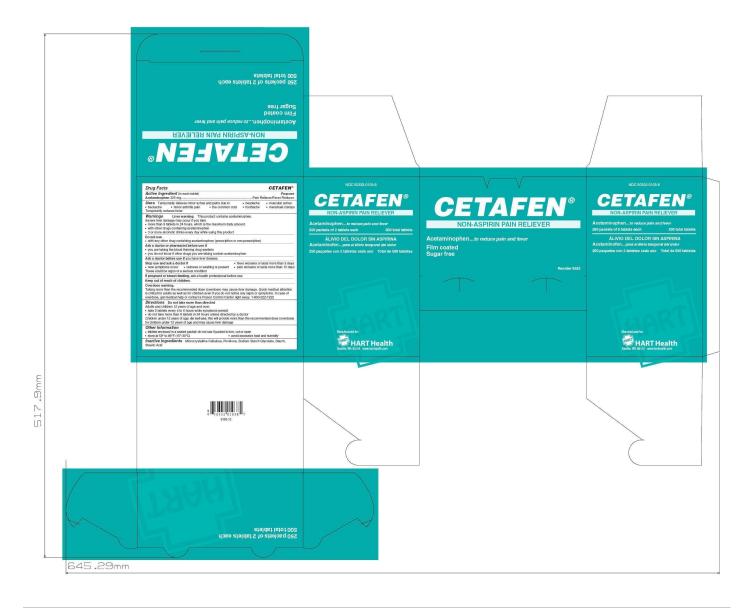
Directions: Do not take more than directed

Adults and children 12 year of age and over:

- take 2 tables every 4 to 6 hours while symptoms persist
- do not take more than 8 tablets 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: Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Starch, Stearic Acid



CETAFEN

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:50332-0103
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	325 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CELLULO SE, MICRO CRYSTALLINE		
POVIDONE		
STEARIC ACID		

Product Characteristics			
Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	CFN
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:50332-0103-4	50 in 1 BOX, UNIT-DOSE		
1	2 in 1 PACKET		
2 NDC:50332-0103-7	125 in 1 BOX, UNIT-DOSE		
2	2 in 1 PACKET		
3 NDC:50332-0103-8	250 in 1 BOX, UNIT-DOSE		
3	2 in 1 PACKET		
4 NDC:50332-0103-1	500 in 1 BOX, UNIT-DOSE		
4	2 in 1 PACKET		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	06/04/1986	

Labeler - HART Health (069560969)

Revised: 11/2012 HART Health