

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

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

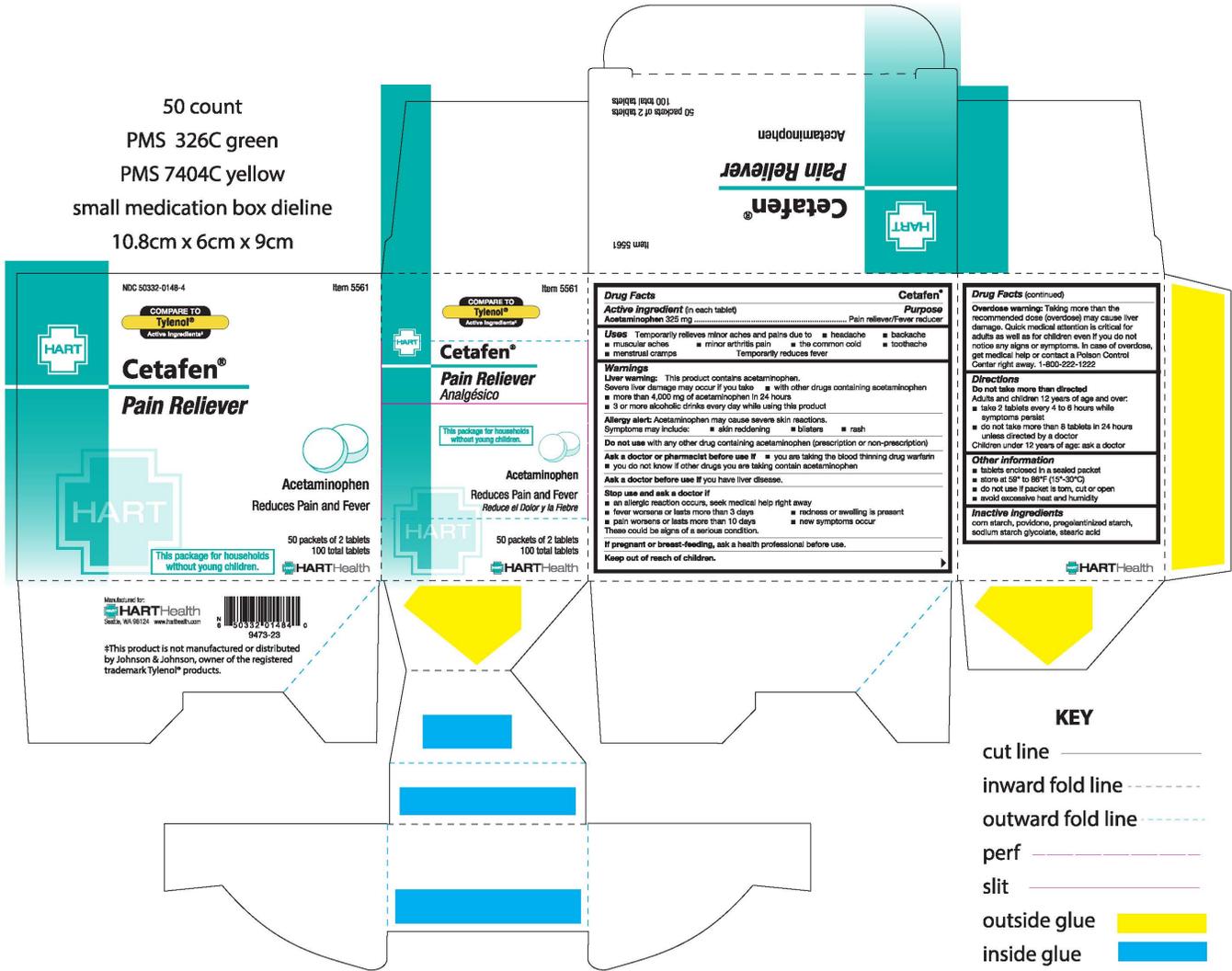
Children under 12 years of age: ask a doctor

Other information:

- tablets 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, povidone, pregelantized starch, sodium starch glycolate, stearic acid

50 count
PMS 326C 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

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0148
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

STEARIC ACID (UNII: 4ELV7Z65AP)

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	AZ;010
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0148-4	50 in 1 BOX, UNIT-DOSE	06/04/1986	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0148-7	125 in 1 BOX, UNIT-DOSE	06/04/1986	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:50332-0148-8	250 in 1 BOX, UNIT-DOSE	06/04/1986	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:50332-0148-1	500 in 1 BOX, UNIT-DOSE	06/04/1986	
4		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	06/04/1986	

Labeler - HART Health (069560969)

Revised: 8/2023

HART Health