

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

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

Inactive Ingredients: Corn Starch, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Stearic Acid

50 count
 PMS 326C green
 PMS 7404C yellow
 small medication box dieline
 10.8cm x 6cm x 9cm

NDC 50332-0103-4 Item 5561

COMPARE TO
Tylenol®
Active Ingredient

Cetafen®
Pain Reliever



Acetaminophen
 Reduces Pain and Fever

50 packets of 2 tablets
 100 total tablets

HART Health

Item 5561

COMPARE TO
Tylenol®
Active Ingredient

Cetafen®
Pain Reliever
Analgesico



Acetaminophen
 Reduces Pain and Fever
Reduce el Dolor y la Fiebre

50 packets of 2 tablets
 100 total tablets

HART Health

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Cetafen®
Pain Reliever

Acetaminophen

Drug Facts

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Drug Facts (continued)

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Other Information
 Tablets enclosed in a sealed packet store at 68° to 88°F (19-32°C).
 Do not use if packet is torn, cut or open.
 Avoid excessive heat and humidity.

Inactive Ingredients
 Corn Starch, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Stearic Acid

Manufactured by:
HART Health
 Seattle, WA 98124 www.harthealth.com

KEY

cut line _____

inward fold line - - - - -

outward fold line - · - · -

perf _____

slit _____

outside glue

inside glue

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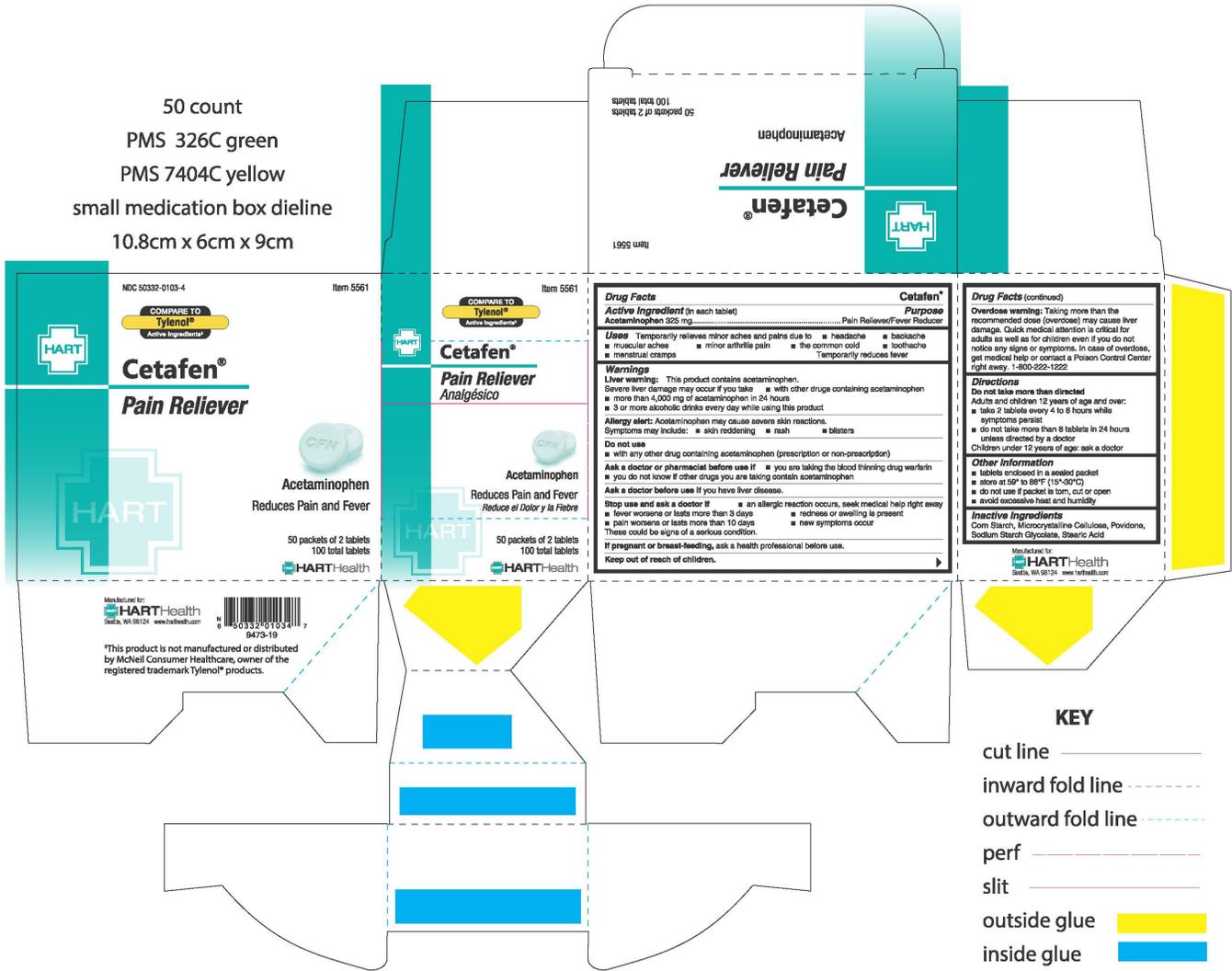
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CETAFEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 332-0 103
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)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)

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	06/04/1986	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0103-7	125 in 1 BOX, UNIT-DOSE	06/04/1986	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:50332-0103-8	250 in 1 BOX, UNIT-DOSE	06/04/1986	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:50332-0103-1	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: 11/2019

HART Health