

CETAFEN COUGH AND COLD- cold medicine 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 COUGH and COLD

Active Ingredients (in each tablet):

Acetaminophen 325 mg

Dextromethorphan HBr 15 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose:

Pain Reliever/Fever Reducer

Cough Suppressant

Expectorant

Nasal Decongestant

Uses:

Temporarily relieves these cold/flu symptoms

- cough
- sore throat
- headache
- minor aches and pains
- nasal congestion
- helps loosen phlegm (mucus) and bronchial secretions to make coughs more productive

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
- blisters
- rash

Sore throat warning:

If sore throat is severe, persists more than 2 days, is accompanied or followed by a fever, headache, rash, nausea or vomiting, consult a doctor right away.

Do not use

- with any other product containing acetaminophen (prescription or non-prescription)
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI)(certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug or if you do not know if your prescription drug contains an MAO.

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

- heart, liver or thyroid disease
- high blood pressure
- diabetes or glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem or a cough with too much phlegm (mucus) or a cough that lasts such as occurs with smoking, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if

- an allergic reaction occurs, seek medical help right away
- new symptoms occur
- you get nervous, dizzy, or sleepless
- pain, nasal congestion or cough gets worse or last for more than 7 days
- redness or swelling is present
- fever gets worse or lasts for more than 3 days
- cough comes back or occurs with rash or headache that lasts

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 call 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:

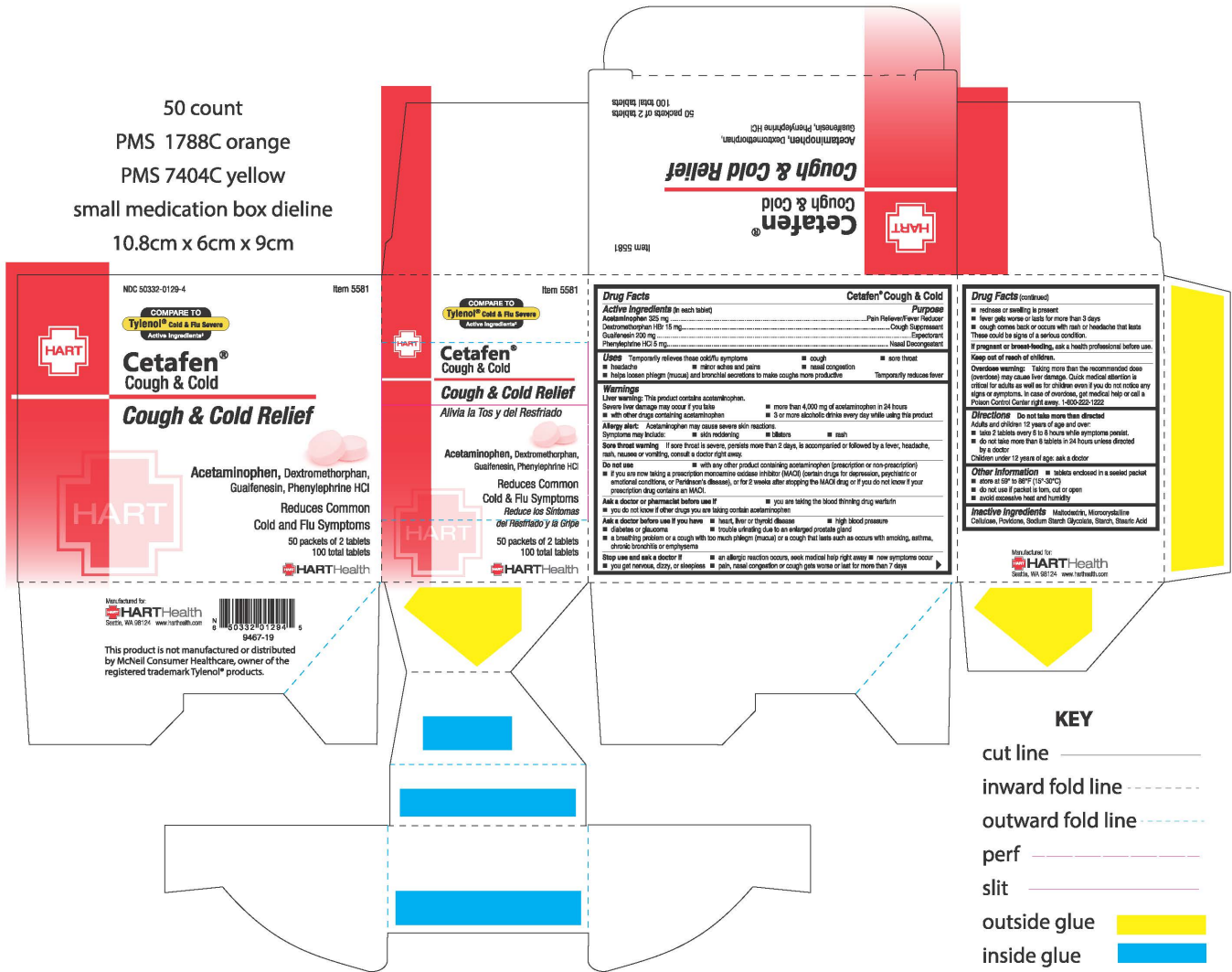
- take 2 tablets every 6 to 8 hours while symptoms persist.

- 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:

Maltodextrin, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Starch, Stearic Acid



50 count
 PMS 1788C orange
 PMS 7404C yellow
 small medication box dieline
 10.8cm x 6cm x 9cm

NDC 50332-0129-4 Item 5581

COMPARE TO
Tylenol® Cold & Flu Severe
Active Ingredient!

Cetafen®
Cough & Cold

Cough & Cold Relief

Acetaminophen, Dextromethorphan,
 Guaifenesin, Phenylephrine HCl

Reduces Common
 Cold and Flu Symptoms

50 packets of 2 tablets
 100 total tablets

HARTHealth

Item 5581

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Alivia la Tos y del Resfriado

Acetaminophen, Dextromethorphan,
 Guaifenesin, Phenylephrine HCl

Reduces Common
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Reduce los Síntomas
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50 packets of 2 tablets
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HARTHealth

100 Tablets
 50 packets of 2 tablets

Acetaminophen, Dextromethorphan,
 Guaifenesin, Phenylephrine HCl

Cetafen®
Cough & Cold

Cough & Cold Relief

Drug Facts
Active Ingredients (in each tablet):
 Acetaminophen 325 mg... Pain Reliever/Fever Reducer
 Dextromethorphan HBr 15 mg... Cough Suppressant
 Guaifenesin 200 mg... Expectorant
 Phenylephrine HCl 5 mg... Nasal Decongestant

Purpose
 Temporarily relieves these bothersome symptoms:
 ■ headache ■ nasal congestion ■ sore throat
 ■ minor aches and pains ■ temporarily reduces fever
 ■ helps loosen phlegm (mucus) and bronchial secretions to make coughs more productive

Warnings
 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

Other information: Acetaminophen may cause severe skin reactions:
 ■ skin redness ■ blisters ■ rash

Do not use
 ■ with any other product containing acetaminophen (prescription or non-prescription)
 ■ if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug or if you do not know if your prescription drug contains an MAOI.

Ask a doctor or pharmacist before use if:
 ■ you are taking the blood thinning drug warfarin
 ■ you have heart, liver or thyroid disease ■ high blood pressure
 ■ diabetes or glucose ■ trouble urinating due to an enlarged prostate gland
 ■ a breathing problem or a cough with too much phlegm (mucus) or a cough that lasts such as occurs with emphysema, asthma, chronic bronchitis or emphysema

Stop use and ask a doctor if:
 ■ an allergic reaction occurs, weak medical help right away ■ new symptoms occur
 ■ you get nervous, dizzy, or sleepless ■ pain, nasal congestion or cough gets worse or last for more than 7 days

Directions
 Do not take more than directed.
 Adults and children 15 years of age and over:
 ■ take 2 tablets every 6 to 8 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
 ■ store at 68° to 78° F (20° to 25° C)
 ■ do not use if packet is torn, cut or open
 ■ avoid excessive heat and humidity

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

Manufactured for:
HARTHealth
 Seattle, WA 98124 www.harthealth.com

KEY

cut line _____

inward fold line - - - - -

outward fold line - · - · -

perf _____

slit _____

outside glue

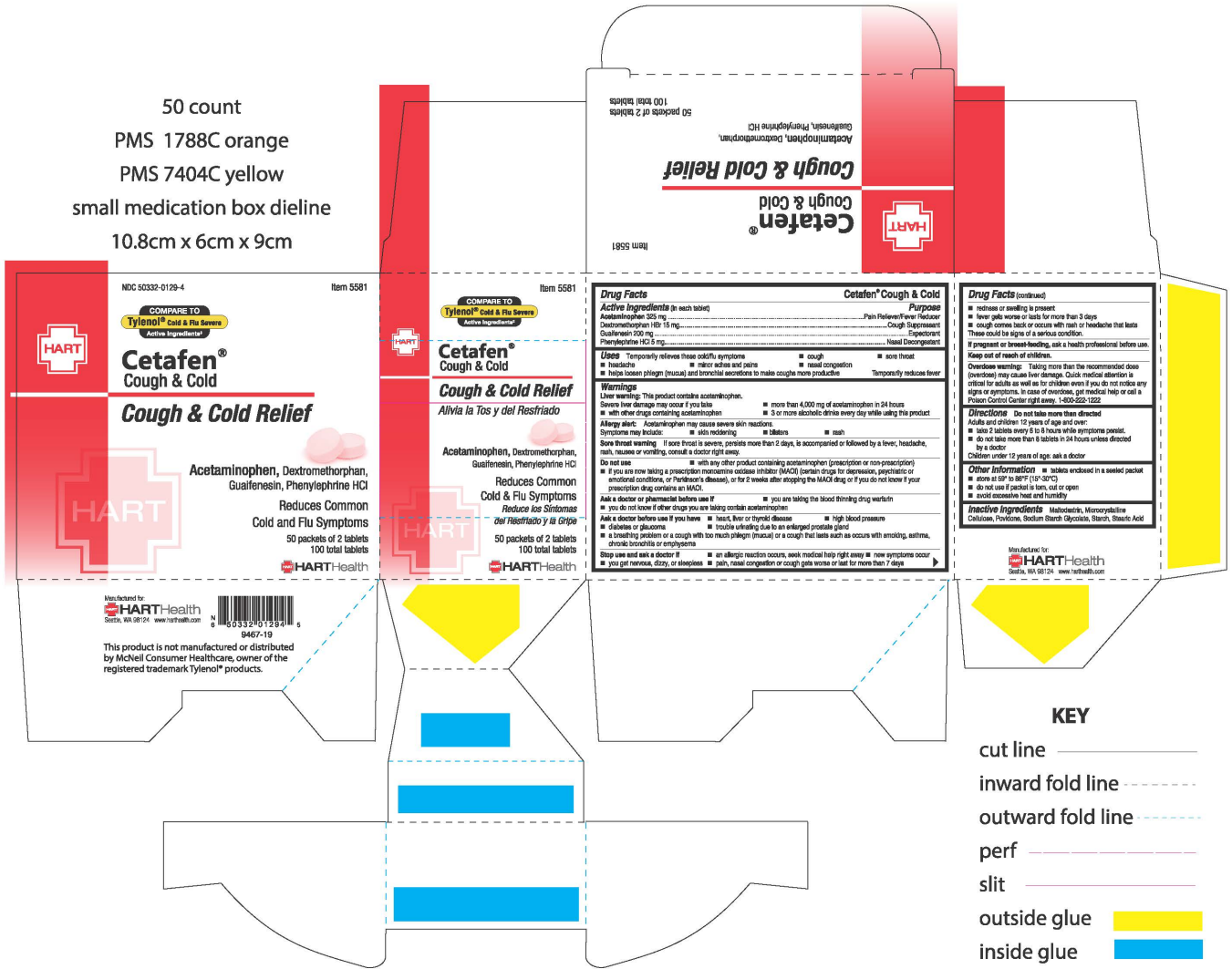
inside glue

Manufactured for
HARTHealth
 Seattle, WA 98124 www.harthealth.com

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This product is not manufactured or distributed
 by McNeil Consumer Healthcare, owner of the
 registered trademark Tylenol® products.

50 count
PMS 1788C orange
PMS 7404C yellow
small medication box dieline
10.8cm x 6cm x 9cm



CETAFEN COUGH AND COLD

cold medicine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 332-0 129
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0129-4	50 in 1 BOX, UNIT-DOSE	03/14/2007	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0129-7	125 in 1 BOX, UNIT-DOSE	03/14/2007	
2		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	03/14/2007	

Labeler - HART Health (069560969)

Revised: 6/2020

HART Health