

**CETAFEN COUGH AND COLD- acetaminophen, dextromethorphan hbr, phenylephrine hcl , guaifenesin, , tablet, film coated  
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.*

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**CETAFEN COUGH and COLD**

***Active ingredients (in each caplet)***

**Acetaminophen** 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 100 mg

Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

***Uses***

Temporarily relieves these cold and flu symptoms

- cough
- sore throat
- headache
- minor aches and pains
- nasal congestion
- sinus congestion and pressure
- helps loosen phlegm (mucus) and bronchial secretions to 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 for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor right away.

**Do not use**

- with any other drug containing acetaminophen (prescription or nonprescription)
- if you have ever had an allergic reaction to this product or any of its ingredients
- 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 before use if you have**

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

**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

**Stop use and ask a doctor if**

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

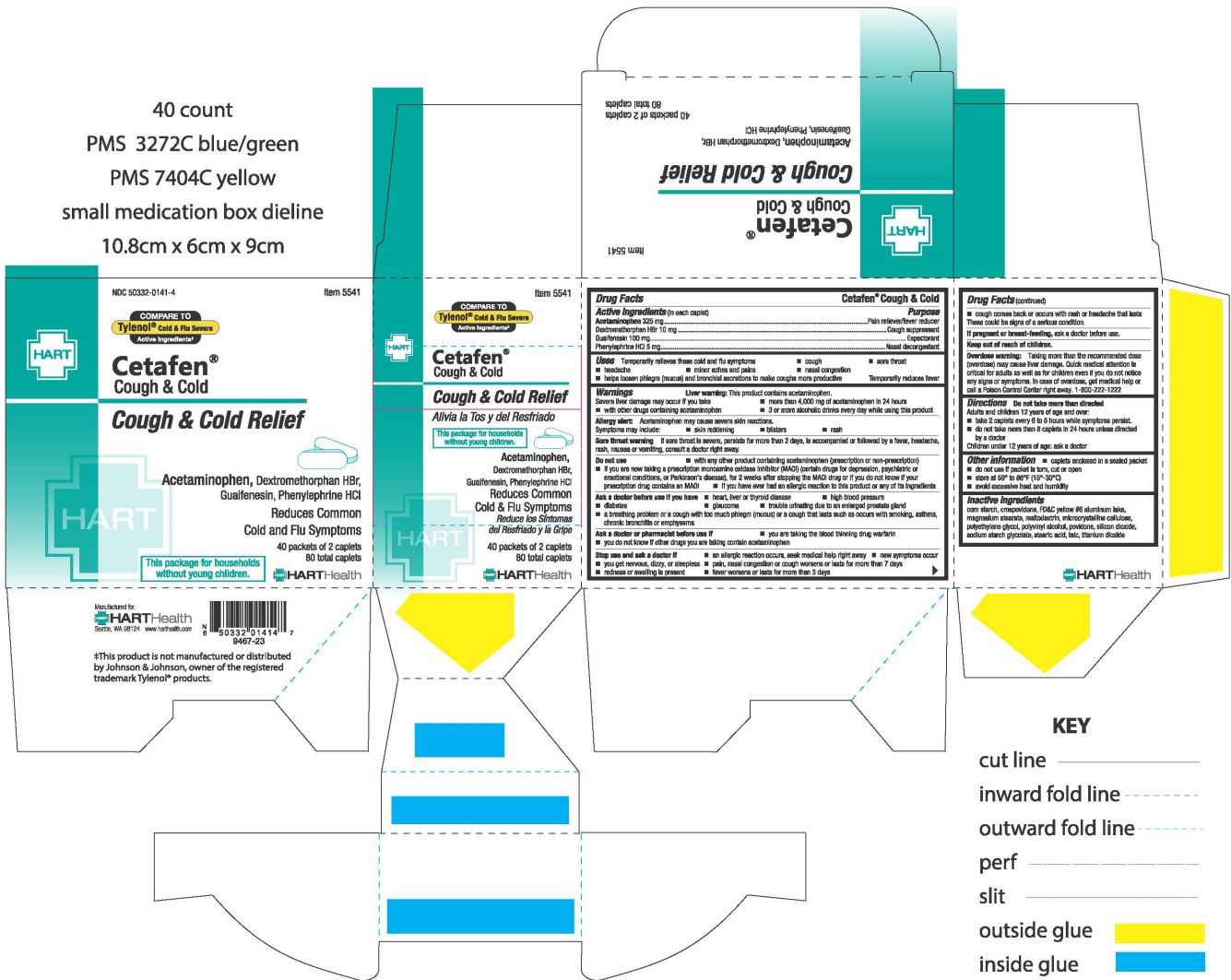
- take 2 caplets every 6 to 8 hours while symptoms persist
- do not take more than 8 caplets in 24 hours unless directed by a doctor

Children under 12 years of age: ask a doctor

**Other information:**

- caplets 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, crospovidone, FD&C yellow # 6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide



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**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50332-0141
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Caplet)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	44;546
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50332-0141-3	20 in 1 BAG	01/09/2023	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0141-4	40 in 1 BOX	01/09/2023	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
	NDC:50332			

3	NDC:50332-0141-7	100 in 1 BOX	01/09/2023	
3		2 in 1 PACKET; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341		01/09/2023	

**Labeler - HART Health (069560969)**

Revised: 8/2023

HART Health