

CETAFEN COUGH AND COLD- acetaminophen, dextromethorphan hbr, phenylephrine hcl , guaifenesin, , tablet, film coated
HART Health

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

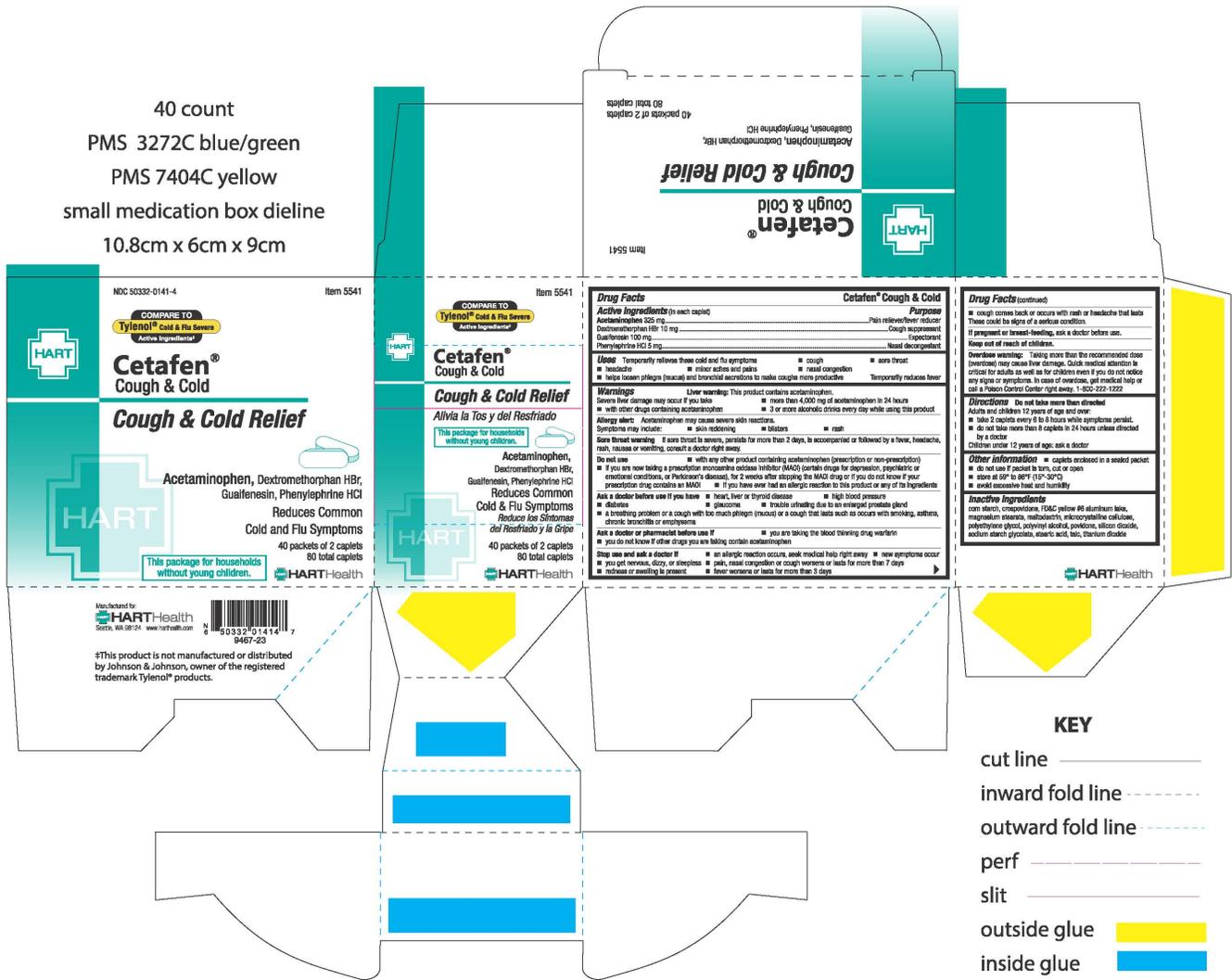
- take 2 caplets every 6 to 8 hours while symptoms persist
- do not take more than 8 caplets in 24 hours unless directed by a doctor

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



CETAFEN COUGH AND COLD			
acetaminophen, dextromethorphan hbr, phenylephrine hcl , guaifenesin, , tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0141
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg

Inactive Ingredients

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

Product Characteristics

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

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		
3	NDC:50332-0141-7	100 in 1 BOX	01/09/2023	
3		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 Drug	M	01/09/2023	

Labeler - HART Health (069560969)

Revised: 12/2025

HART Health