

GOOD NEIGHBOR PHARMACY COLD MULTI SYMPTOM- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated Amerisource Bergen

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.

Amerisource Bergen Cold Drug Facts

Active ingredient (in each caplet)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- for the temporary relief of the following cold/flu symptoms:
- minor aches and pains
- sore throat
- cough
- headache
- nasal congestion
- impulse to cough
- helps loosen phlegm (mucus) and thin 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 12 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

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 promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not use more than directed

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- new symptoms occur
- fever gets worse or lasts more than 3 days
- cough comes back or occurs with rash or headache that lasts
- redness or swelling is present

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.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222) Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed (see Liver warning)

adults and children 12 years and over	<ul style="list-style-type: none">• take 2 caplets every 4 hours• swallow whole – do not crush, chew or dissolve• do not take more than 12 caplets in 24 hours
children under 12 years	<ul style="list-style-type: none">• do not use this adult product in children under 12 years of age

Other information

- each caplet contains: sodium 3 mg

Inactive ingredients

acesulfame potassium, carnauba wax, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, flavor, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

See New Warnings Information

Compare To Active Ingredients In Tylenol® Cold Multi-Symptom Severe Cool Burst® Caplets
Cold

Multi-Symptom

Severe

Pain Reliever/Fever Reducer, Nasal Decongestant, Cough Suppressant, Expectorant

Contains 4 Medicines:

Fever/Headache/Sore Throat – Acetaminophen

Nasal Congestion – Phenylephrine HCl

Coughing – Dextromethorphan HBr

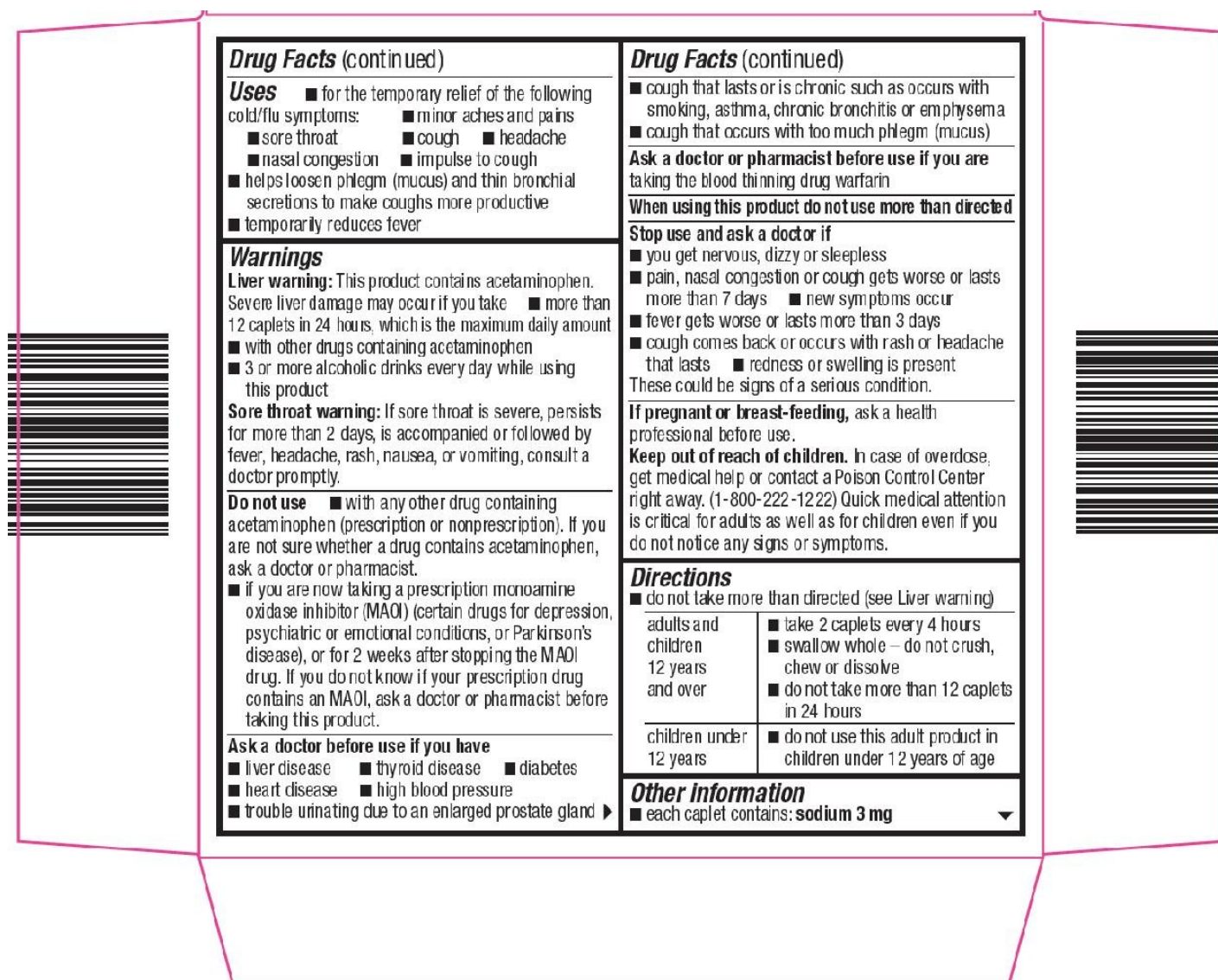
Chest Congestion – Guaifenesin

Cool Ice® Instant Cooling Sensation

Daytime

Non-Drowsy

Cold Carton Image 1



Cold Carton Image 2

GOOD NEIGHBOR PHARMACY COLD MULTI SYMPTOM

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24385-066
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	10 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	
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)				
CROSPVIDONE (UNII: 68401960MK)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
POLYVINYL ALCOHOL (UNII: 532B59J990)				
POVIDONE (UNII: FZ989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)				
Product Characteristics				
Color	YELLOW		Score	no score
Shape	OVAL (capsule shaped)		Size	20mm
Flavor	VANILLA (menthol)		Imprint Code	L234
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24385-066-62	2 in 1 CARTON		
1		12 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph final	part341		03/30/1993	

Labeler - Amerisource Bergen (007914906)