

**COLD MULTI-SYMP TOM- acetaminophen, dextromethorphan hbr,
phenylephrine hcl tablet, coated
Allegiant Health**

324 - Health A2Z Cold Multi-Symptom

Active ingredient(s)

Acetaminophen 325mg

Dextromethorphan HBr 10mg

Phenylephrine HCl 5mg

Purpose

Pain reliever/fever reducer

Cough suppressant

Nasal decongestant

Uses

- temporarily relieves these common cold/flu symptoms:
- minor aches and pains
- headache
- sore throat
- nasal congestion
- cough
- sinus congestion and pressure
- 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

Allergy alert: acetaminophen may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help immediately

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 products containing acetaminophen (prescription or nonprescription).

If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. Do not use 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 drugs). If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist.

Ask a doctor before use if you have

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

Ask a doctor before use if you are

taking the blood thinning drug warfarin

When using this product

When using this product do not exceed recommended dosage

Stop use and ask a doctor if

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occurs
- pain gets worse or lasts more than 7 days or fever gets worse or lasts more than 3 days
- redness or swelling is present or new symptoms occur

- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

Pregnancy/Breastfeeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately. 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.

Directions

do not take more than directed (see **Warnings**)

Adults and children 12 years and over:

- take 2 caplets every 4 hours
- do not take more than 12 caplets in 24 hours

Children under 12 years: do not use this adult product in children under 12 years of age.

This will provide more than the recommended dose (overdose) and may cause liver damage

Other information

- store between 15-30°C (59-86°F)
- do not use if blister is torn or open

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, hydroxypropylmethylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide

Questions or comments?

Call toll free 1-888-952-0050

Principal Display Panel



HealthA2Z® *Compare to active ingredients in Tylenol® Cold Multi-Symptom Daytime

COLD DAYTIME NON-DROWSY MULTI-SYMPTOM

Acetaminophen/Dextromethorphan HBr/Phenylephrine HCl

Relieves sore throat, cough and nasal congestion



12 Caplets

See new warnings information



Lot: Exp.

Drug Facts (continued)
Other information ■ store between 15-30°C (59-86°F) ■ do not use if blister is torn or open
Inactive ingredients colloidal silicon dioxide, corn starch, croscarmellose sodium, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide
Questions or comments?
 Call toll free 1-888-952-0050
Drug Facts (continued)

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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 ■ 3 or more ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product ■ 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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist.
 Ask a doctor before use if you have ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with asthma ■ persistent or chronic cough such as occurs with asthma ■ persistent or chronic cough such as occurs with asthma
Do not use ■ with any other products 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 drugs. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist.
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Stop use and ask a doctor if ■ nervousness, dizziness or sleeplessness occurs ■ pain gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ 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.** In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately. 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. **Directions** Do not take more than directed (see Warnings). Adults and children 12 years and over: ■ take 2 caplets every 4 hours ■ do not take more than 12 caplets in 24 hours. Children under 12 years: do not use this adult product in children under 12 years of age. This will provide more than the recommended dose (overdose) and may cause liver damage.
Drug Facts (continued)
 smoking, asthma, or emphysema ■ cough that occurs with too much phlegm (mucus) ■ Ask a doctor before use if you are taking the blood thinning drug warfarin
When using this product do not exceed recommended dosage
Stop use and ask a doctor if ■ nervousness, dizziness or sleeplessness occurs ■ pain gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur ■ cough comes back or occurs with rash or headache that lasts These could be signs of a serious condition.
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Drug Facts (continued)

Manufactured by:
AH Alleghant Health
 Deer Park, NY 11729
 LB0883
 R0815
 *This product is not manufactured or distributed by McKell Consumer Healthcare, owner of the registered trademark Tylenol® Cold Multi-Symptom Daytime.

LEBG761H2

Cold Multi-Symptom

COLD MULTI-SYMPTOM
 acetaminophen, dextromethorphan hbr, phenylephrine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-324
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	AZ;324
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-324-86	1 in 1 CARTON	08/15/2015	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/15/2015	

