

COLD MULTI-SYMPTOM DAY-TIME- acetaminophen, guaifenesin, dextromethorphan hbr and phenylephrine hci tablet

Allegiant 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.

Drug Facts

Active ingredient

Acetaminophen 325 mg

Guaifenesin 200 mg

Dextromethorphan HBr 10 mg

Phenylephrine HCl 5 mg

Purpose

Analgesic/Antipyretic

Expectorant

Cough suppressant

Decongestant

Uses

for the temporary relief of the following cold/flu symptoms: •minor aches and pains • headache • sore throat •nasal congestion •cough •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 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 before taking this product

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 ■ cough that occurs with too much phlegm (mucus) ■ persistent or chronic cough such 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 taking sedatives or tranquilizers

When using this product

do not use exceed recommended dosage

Stop use and ask a doctor if

■ nervousness, dizziness, or sleeplessness occur ■ pain, nasal congestion or cough gets worse or lasts for more than 7 days ■ fever gets worse or lasts for 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 overdose, contact a Poison Control Center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

Directions

Adults and children 12 years and over: take 2 caplets every 4 hours ■ do not take more than a total of 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 recommended dose (overdose) and may cause liver damage

Other Information

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

Inactive Ingredients

corn starch, croscarmellose sodium, crospovidone, FD&C Yellow #10, hydroxypropyl methylcellulose, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

Call toll free 1-888-952-0050

Package/Label Principal Display Panel

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 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)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONES (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSPVIDONE (UNII: 68401960MK)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	AZ323
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-323-86	12 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/23/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/23/2014	

Labeler - Allegiant Health (079501930)

Registrant - Allegiant Health (079501930)**Establishment**

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	ANALYSIS(69168-323) , LABEL(69168-323) , MANUFACTURE(69168-323) , PACK(69168-323) , RELABEL(69168-323) , REPACK(69168-323)

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