

BRONCHIAL ASTHMA RELIEF - ephedrine hcl, guaifenesin tablet

Walgreens Company

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.

Bronchial Asthma Relief

Drug Facts

ACTIVE INGREDIENT

(in each tablet)

Ephedrine HCl, USP 12.5 mg

Guaifenesin, USP 200 mg

PURPOSE

Bronchodilator

Expectorant

INDICATIONS AND USAGE

- for temporarily relief of mild symptoms of intermittent asthma:
- wheezing
- tightness of chest
- shortness of breath
- helps loosen phlegm (mucus) and thin bronchial secretions to rid bronchial passageways of bothersome mucus, and make coughs more productive

WARNINGS

Asthma alert: Because asthma may be life threatening, see a doctor if you

- are not better in 60 minutes
- get worse
- need 12 tablets in any day
- use more than 8 tablets a day for more than 3 days a week
- have more than 2 asthma attacks a week

These may be signs that your asthma is getting worse

DO NOT USE

- unless a doctor said you have asthma
- if you are now taking prescription monoamine oxidase inhibitor (MAOI) (certain drugs taken 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 DOCTOR

before use if you have:

- ever been hospitalized for asthma
- heart disease
- high blood pressure
- diabetes
- thyroid disease
- seizures
- narrow angle glaucoma
- a psychiatric or emotional condition
- trouble urinating due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

ASK DOCTOR/PHARMACIST**before use if you are**

- taking prescription drugs for asthma, obesity, weight control, depression, or psychiatric or emotional conditions
- taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as for allergy, cough-cold, or pain)

STOP USE**and ask a doctor if**

- your asthma is getting worse (see Asthma alert)
- you have difficulty sleeping
- you have rapid heartbeat
- you have tremors, nervousness, or seizure
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache, these could be signs of a serious condition.

WHEN USING**this product**

- **your blood pressure or heart rate may go up. This could increase your risk of heart attack or stroke, which may cause death.**
- **your risk of heart attack or stroke increases if you:**
- **have a history of high blood pressure or heart disease**
- **take this product more frequently or take more than the recommended dose**
- avoid foods or beverages that contain caffeine
- avoid dietary supplements containing ingredients reported or claimed to have a stimulant effect

PREGNANCY OR BREAST FEEDING

ask a health professional before use.

KEEP OUT OF REACH OF CHILDREN

In case of overdose, get medical help or contact Poison Control Center right away.

DOSAGE AND ADMINISTRATION

- **do not exceed dosage**
- this adult product is not intended for use in children under 12 years of age

adults and children 12 years of age and over take 1-2 tablets every 4 hours as needed, not to exceed 12 tablets in 24 hours
children under 12 years of age ask a doctor

Other information

store at room temperature, USP

INACTIVE INGREDIENT

D&C Yellow #10 Lake, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Povidone, Silica and Stearic Acid

REV 05/12

Intentional abuse of this product can be harmful or fatal

Distribution of this product requires a DEA License

Tamper evident: Do Not USE IF CARTON HAS BEEN OPENED OR BLISTER UNITS ARE TORN OR BROKEN

GLUTEN FREE

‡Walgreens Pharmacist Survey Study, November 2010

#This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Primatene®

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

WALGREENS PHARMACIST RECOMMENDED‡

Ephedrine HCl, USP 12.5 mg/ Bronchodilator

Guaifenesin, USP 200 mg/ Expectorant

- Helps breathing without drowsiness
- Restores free breathing
- Loosens phlegm

Compare to Primatene®

active ingredients#

MAXIMUM SALE: ONE PACKAGE PER CUSTOMER

NOT FOR SALE TO MINORS



BRONCHIAL ASTHMA RELIEF

ephedrine hcl, guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-2529
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
EPHEDRINE HYDROCHLORIDE (UNII: NLJ6390P1Z) (EPHEDRINE - UNII:GN83C131XS)	EPHEDRINE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	YELLOW (pale yellow)	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor		Imprint Code	CPC;2529
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-2529-67	4 in 1 CARTON		
1		15 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/13/2002	

Labeler - Walgreens Company (008965063)

Registrant - Contract Pharmaco Corp (968334974)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmaco Corp		968334974	MANUFACTURE(0363-2529)

Revised: 9/2012

Walgreens Company