

**PRIMATENE- ephedrine hydrochloride and guaifenesin tablet**  
**Pfizer Consumer Healthcare**

*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.*

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**Primatene® Tablets**

**DRUG FACTS**

**ACTIVE INGREDIENTS (IN EACH TABLET)**

Ephedrine HCl, USP 12.5 mg

Guaifenesin, USP 200 mg

**PURPOSES**

Bronchodilator

Expectorant

**USES**

- for temporary 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 to 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 more than 12 tablets in 24 hours
- use more than 8 tablets in 24 hours for 3 or more days a week
- have more than 2 asthma attacks in a week

These may be signs that your asthma is getting worse

- This product will not give you asthma relief as quickly as an inhaled bronchodilator

**Do not use**

- unless a doctor said you have asthma
- if you are now taking a 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 a 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 an enlarged 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 a doctor or 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 a rapid heart beat
- you have tremors, nervousness, or seizure
- cough lasts more than 7 days, comes back, or is accompanied by 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

**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.

**DIRECTIONS**

- **do not take more than directed**

<b>age</b>	<b>dose</b>
adults and children 12 years of age and over	oral dose is 1-2 tablets (12.5 to 25 mg) every 4 hours as needed. Do not take more than 12 tablets (150 mg) in 24 hours
children under 12 years of age	ask a doctor

**OTHER INFORMATION**

- store at 20-25°C (68-77°F)

## **INACTIVE INGREDIENTS**

colloidal silicon dioxide, crospovidone, D&C yellow no. 10 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, povidone

## **QUESTIONS OR COMMENTS?**

Call weekdays from 9 AM to 5 PM EST at **1-800-535-0026**

For most recent product information, visit [www.PrimateneTablets.com](http://www.PrimateneTablets.com)

## **PRINCIPAL DISPLAY PANEL - 60 Tablet Carton**

**Primatene®**

**TABLETS**

Ephedrine HCl, Bronchodilator/Guaifenesin, Expectorant  
Helps Loosen Phlegm (Mucus)

*For the Temporary Relief of Mild Symptoms of*

**INTERMITTENT ASTHMA**

**60 TABLETS**

**Primatene<sup>®</sup>  
TABLETS**

Pfizer, Madison, NJ 07940 USA © 2011 Pfizer Inc.  
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**Drug Facts (continued)**  
Inactive ingredients  
crotal silt on dicide, crospondone,  
D&C yellow no. 10 aluminum lake, FD&C yellow no. 6  
aluminum lake, magnesium stearate, microcrystalline  
cellulose, povidone  
**Questions or comments?**  
Call weekdays from 9 AM to 5 PM EST at  
1-800-535-0026

**Other information** ■ store at 20-25°C (68-77°F)

adults and children 12 years of age and over	oral dose is 1-2 tablets (12.5 to 25 mg) every 4 hours as needed. Do not take more than 12 tablets (150 mg) in 24 hours
children under 12 years of age	ask a doctor

**Directions**  
■ do not take more than directed

**Drug Facts (continued)**  
■ you have tremors, nervousness, or seizure  
■ cough lasts more than 7 days, comes back, or is accompanied by 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 the product more frequently or take more than the recommended dose  
■ avoid dairy supplements containing ingredients reported or avoid foods or beverages that contain caffeine  
■ avoid dairy supplements containing ingredients reported or claim to have a stimulant effect.  
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.

**Drug Facts (continued)**  
Do not use  
■ unless a doctor said you have asthma  
■ if you are now taking a prescription maintenance inhaler (MDI) (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 a doctor before use if you have  
■ ever been hospitalized for asthma  
■ heart disease ■ high blood pressure  
■ diabetes ■ thyroid disease  
■ seizures ■ narrow angle glaucoma  
■ psychiatric or emotional condition  
■ trouble urinating due to an enlarged 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 a doctor or 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 theophylline, pseudoephedrine, ephedrine, or caffeine (such as for alert, cough-cold, or pain)  
■ your asthma is getting worse (see Asthma alert)  
■ you have difficulty sleeping  
■ you have a rapid heart beat

EACH TABLET IS INDIVIDUALLY SEALED.  
USE ONLY IF SEAL IS INTACT.  
INTENTIO NAL AB USE OF THIS PRO DUCT  
CAN BE HARMFUL OR FATAL

**Drug Facts (continued)**  
**Warnings**  
Asthma alert: Because asthma may be life threatening, see a doctor if you  
■ are not better in 60 minutes ■ get worse  
■ need more than 12 tablets in 24 hours  
■ use more than 8 tablets in 24 hours for 3 or more days a week  
These may be signs that your asthma is getting worse  
■ These signs may be signs that your asthma is getting worse  
■ This product will not give you asthma relief as quickly as an inhaled bronchodilator

**Drug Facts**  
**Active ingredients (in each tablet)** Purpose  
Ephedrine HCl, USP 12.5 mg .....Bronchodilator  
Guaifenesin, USP 200 mg .....Expectorant  
**Uses**  
■ for temporary 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 both mucus, and to make coughs more productive

PA0025246

128 CODE AREA



**Primatene<sup>®</sup>  
TABLETS**  
Ephedrine HCl, Bronchodilator/Guaifenesin, Expectorant  
Helps Loosen Phlegm (Mucus)

For the Temporary Relief of Mild Symptoms of  
**INTERMITTENT ASTHMA**



60 TABLETS



128 CODE AREA

# PRIMATENE

ephedrine hcl, guaifenesin tablet

## Product Information

Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0573-2952
Route of Administration	ORAL	DEA Schedule	

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPHEDRINE HYDROCHLORIDE (EPHEDRINE)	EPHEDRINE HYDROCHLORIDE	12.5 mg
GUAIFENESIN (GUAIFENESIN)	GUAIFENESIN	200 mg

## Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE	
CROSPVIDONE	
D&C YELLOW NO. 10	
FD&C YELLOW NO. 6	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONES	

## Product Characteristics

Color	YELLOW (Light yellow color)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	P;in;circle;engraved;bisect
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2952-10	2 in 1 CARTON		
1		12 in 1 BLISTER PACK		
2	NDC:0573-2952-20	5 in 1 CARTON		
2		12 in 1 BLISTER PACK		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC MONOGRAPH FINAL	part341	01/06/2004	
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**Labeler** - Pfizer Consumer Healthcare (828831730)

**Establishment**

Name	Address	ID/FEI	Business Operations
Wyeth Pharmaceuticals Company, Consumer Site		829390975	ANALYSIS(0573-2952), LABEL(0573-2952), MANUFACTURE(0573-2952), PACK(0573-2952)

Revised: 2/2013

Pfizer Consumer Healthcare