

PRIMATENE- ephedrine hydrochloride tablet
Foundation Consumer Brands

Primatene ®

Drug Facts

Active ingredient (in each tablet)

Ephedrine HCl 12.5 mg

Purpose

Bronchodilator

Use

- for temporary relief of mild symptoms of intermittent asthma:
 - wheezing
 - tightness of chest
 - shortness of breath

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.
- if you have ever had an allergic reaction to this product or any of its ingredients

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

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)

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

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

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**
- adults and children 12 years and over: take 1-2 tablets every 4 hours as needed. Do not take more than 12 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

D&C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate, FD&C yellow #6

aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium starch glycolate, stearic acid

Questions or comments?

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

Distributed by:
Foundation Consumer Brands, LLC
Pittsburgh, PA 15212

PRINCIPAL DISPLAY PANEL - 12.5 mg Tablet Blister Pack Carton

NEW FORMULA

Primatene[®]
TABLETS

Ephedrine HCl 12.5 mg • Bronchodilator

For the Temporary Relief of Mild Symptoms of
INTERMITTENT ASTHMA

24 TABLETS

Distributed by:
Foundation Consumer Brands, LLC
Pittsburgh, PA 15212 ©2020
primatene-tablets.com

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Primatene®

TABLETS
Ephedrine HCl 12.5 mg • Bronchodilator

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NEW FORMULA



Primatene®
TABLETS

Ephedrine HCl 12.5 mg • Bronchodilator

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



Drug Facts
Active ingredient (in each tablet) Purpose
Ephedrine HCl 12.5 mg.....Bronchodilator

Use ■ for temporary relief of mild symptoms of intermittent asthma; ■ wheezing ■ tightness of chest

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. ■ If you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have
■ ever been hospitalized for asthma ■ heart disease ■ high blood pressure ■ diabetes ■ thyroid disease ■ seizures ■ a psychiatric or emotional condition ■ trouble urinating due to an enlarged prostate gland

Drug Facts (continued)
Inactive ingredients D&C yellow #1 aluminum lake, dibasic calcium phosphate dihydrate, FD&C yellow #5 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide, sodium starch glycolate, stearic acid

Drug Facts (continued)

Questions or comments? Call 1-800-535-0026 weekdays 9 AM to 5 PM EST

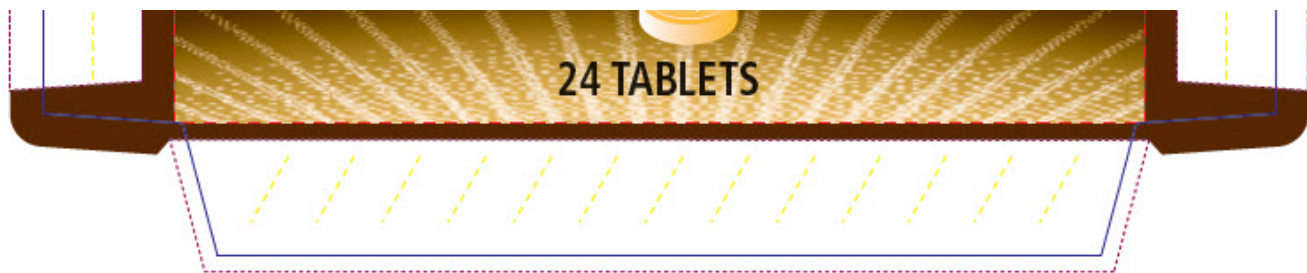
Other information ■ store at 20-25°C (68-77°F) ■ children under 12 years of age: do not use

Directions ■ do not take more than directed ■ adults and children 12 years and over: take 1-2 tablets every 4 hours as needed. Do not take more than 12 tablets in 24 hours

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. ■ If pregnant or breast-feeding, ask a health professional before use. ■ you have asthma is getting worse (see Asthma alert) ■ you have difficulty sleeping ■ you have a rapid heart beat ■ you have tremors, nervousness, or shakiness

Stop use and ask 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 shakiness ■ 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)
Ask a doctor or pharmacist before use if you are ■ taking prescription drugs for asthma, dosing by weight ■ taking any drug that contains phenylephrine, pseudoephedrine, ephedrine, or caffeine (such as for allergy, cough-cold, or pain) ■ 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. ■ you 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 or claimed to have a stimulant effect



PRIMATENE

ephedrine hydrochloride tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80070-600
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80070-600-24	2 in 1 CARTON	01/22/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2	NDC:80070-600-60	5 in 1 CARTON	01/22/2021	
2		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		M012	01/22/2021	

Labeler - Foundation Consumer Brands (117603632)

Revised: 11/2024

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