

PRIMATENE- ephedrine hydrochloride tablet
Foundation Consumer Brands

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.

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

120420



Primatene

TABLETS
 Ephedrine HCl 12.5 mg • Bronchodilator

B-0518-767-08
 ORG12076708

NEW FORMULA

Primatene[®] TABLETS

Ephedrine HCl 12.5 mg • Bronchodilator

For the Temporary Relief of Mild Symptoms of
INTERMITTENT ASTHMA



Drug Facts (continued)
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 ■ 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 ■ This product will not give you asthma relief as quickly as an inhaled bronchodilator.

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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

Drug Facts (continued)
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Drug Facts (continued)
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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 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 ■ you have dizziness or lightheadedness ■ you have a headache ■ you have a change in voice ■ you have a change in taste ■ you have a change in vision ■ you have a change in hearing ■ you have a change in smell ■ you have a change in taste ■ you have a change in vision ■ you have a change in hearing ■ you have a change in smell

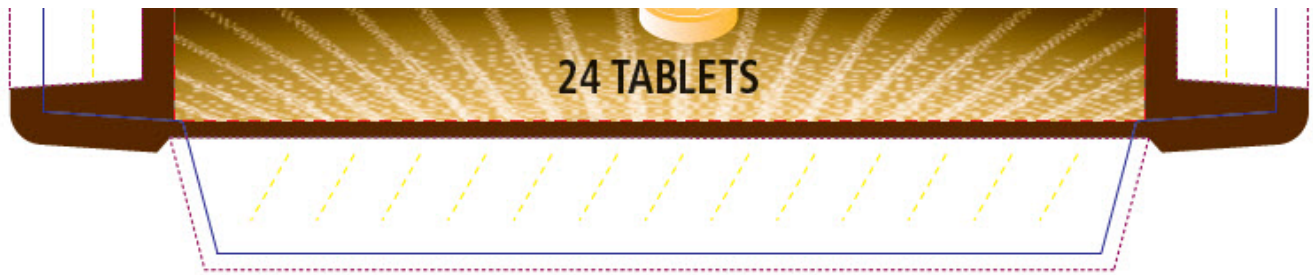
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Other information ■ store at 20-25°C (68-77°F) ■

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



DO NOT USE IF PASTEL IS CUT OR BROWNEN
 KEEP OUTER CARTON FOR COMPLETE PRODUCT INFORMATION



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	8 mm
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 FINAL	part341	01/22/2021	

Labeler - Foundation Consumer Brands (117603632)

Revised: 1/2021

Foundation Consumer Brands