EPHED ASTHMA- ephedrine hydrochloride, guaifenes in tablet Dickey Consumer Products DBA DMD

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(In Each Tablet): Ephedrine HCl 25 mg, Guaifenesin 200 mg

Purposes - Bronchodilator, Expectorant

• 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.

As thma Alert: because asthma may be life threatening, see a doctor if you: • Are not better in 60 minutes • get worse • need more than 6 tablets in 24 hours • use more than 4 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 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 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)

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 food or beverages that contain caffeine • Avoid dietary supplements containing ingredients reported or claim 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 seizures • cough lasts more than 1 week, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

If pregnant or breast feeding, ask a health proffessional before use

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

• do not take more than directed • adults and children 12 years of age and over: 1 tablet every 4 hours as needed, do not take more than 6 tablets in 24 hours • children under 12 years of age: do not use

Inactive Ingredients: Maltodextrin, Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Stearic Acid



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Expectorant Bronchodilator

Active ingredients (in each tablet) Drug Facts

səsodınd

Use only if seal is intact. (68°F - 77°F) ■ Tamper-evident: Each tablet is individually sealed. Other Information III store in a cool dry place between 20°C - 25°C

more than 6 tablets in 24 hours 🔳 children under 12 years of age: do not use years of age and over: oral dose is 1 tablet every 4 hours as needed, do not take Directions

and children 12

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Drug Facts (continued)

LOG BOOK ITEM



dmdpharm.com NON-DROWSY Ephedrine HCI 25 mg, Bronchodilator • Guaifenesin 200 mg, Expectorant TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS



INTENTIONAL ABUSE OF THIS CAN BE HARMFUL OR FATAL

Ouestions? 1-800-755-2477 Mon-Fri 9am-5pm ES∃ mq2-ms6 in-Fri Mon-Fri 9am-com

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Drug Facts (continued)

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Drug Facts (continued)

LOG BOOK ITEM



dmdpharm.com NON-DROWSY Ephedrine HCI 25 mg, Bronchodilator • Guaifenesin 200 mg, Expectorant TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS



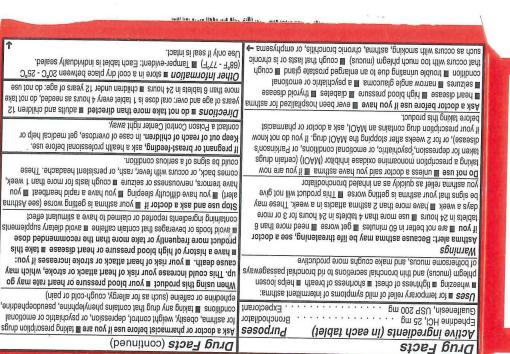
INTENTIONAL ABUSE OF THIS CAN BE HARMFUL OR FATAL

Ouestions? 1-800-755-2477 Mon-Fri 9am-5pm ES∃ mq2-ms6 in-Fri Mon-Fri 9am-com

Inactive ingredients: magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate,

Drug Facts (continued)

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3

Drug Facts (continued)

EPHED ASTHMA

ephedrine hydrochloride, guaifenesin tablet

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65193-320	
Route of Administration	ORAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
EPHEDRINE HYDRO CHLO RIDE (UNII: NLJ6390P1Z) (EPHEDRINE - UNII:GN83C131XS)	EPHEDRINE HYDROCHLORIDE	25 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	

Inactive Ingredients		
Ingredient Name	Strength	
PO VIDONE K30 (UNII: U725QWY32X)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)		
MALTO DEXTRIN (UNII: 7CVR7L4A2D)		

Product Characteristics			
Color	white (snow white)	Score	4 pieces
Shape	ROUND (EP225)	Size	9 mm
Flavor		Imprint Code	EP225
Contains			

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:65193-320-24	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/13/2011	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/13/2011	

Labeler - Dickey Consumer Products DBA DMD (835974056)

Registrant - Dickey Consumer Products DBA DMD (835974056)

Establishment			
Name	Address	ID/FEI	Business Operations
Ultratab Laboratories, Inc.		151051757	manufacture(65193-320)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corp.		085752004	pack(65193-320)

Revised: 3/2019

Dickey Consumer Products DBA DMD