

EPHED PLUS- ephedrine hydrochloride, guaifenesin 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.

Asthma 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 professional 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

<p>Drug Facts (continued)</p> <p>Active Ingredients (in each tablet)</p> <p>Ephedrine HCl, 25 mg Guaifenesin, USP 200 mg</p> <p>Purposes</p> <p>Bronchodilator Expectorant</p> <p>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)</p> <p>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</p> <p>Stop use and ask a doctor if your asthma is getting worse (see Asthma alert) you have difficulty sleeping you have a rapid heartbeat you have tremors, nervousness or seizure cough lasts for more than 1 week, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>Directions do not take more than directed adults and children 12 years of age and over: oral dose is 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</p> <p>Other Information store in a cool dry place between 20°C - 25°C (68°F - 77°F) Tamper-evident: Each tablet is individually sealed. Use only if seal is intact.</p>	<p>Drug Facts</p> <p>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</p> <p>Warnings</p> <p>Asthma 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 asthma relief as quickly as an inhaled bronchodilator</p> <p>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.</p> <p>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 psychotropic or emotional condition ■ trouble urinating due to an enlarged prostate gland ■ cough ■ cough that occurs with too much phlegm (mucus) ■ cough that lasts or is chronic ■ such as occurs with smoking, asthma, chronic bronchitis, or emphysema</p>
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Ephed Plus EP 225

TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS

NON-DROWSY

Ephedrine Plus EP 225

Ephedrine HCl 25 mg, Bronchodilator • Guaifenesin 200 mg, Expectorant

TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS

HELPS RESTORE BREATHING AND LOOSENS PHEGM

24 TABLETS

GMD Pharmaceuticals

LOG BOOK ITEM

Manufactured by **GMD Pharmaceuticals**
A Division of Drexel Corporation, Philadelphia, PA
Non-drowsy in 40660

INTENTIONAL ABUSE OF THIS PRODUCT CAN BE HARMFUL OR FATAL

0 98443 24055 8

Drug Facts (continued)

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

Questions? 1-800-795-2477 Mon-Fri 9am-5pm EST visit us at: dmdpharm.com

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EP 225

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DMD Pharmaceuticals

24 TABLETS

dmdpharm.com

Manufactured by
DMD Pharmaceuticals
A Division of Dandy Consumer Products, Inc.
Indolepsville, IN 46060

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CAN BE HARMFUL OR FATAL

0 98443 24055 8

Drug Facts (continued)
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Drug Facts

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Guaifenesin, USP 200 mg
Expectorant

Purposes
Bronchodilator 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)

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 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 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 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

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

Use only if seal is intact.

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

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.

comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious condition.

Stop use and ask a doctor if ■ your asthma is getting worse (see Asthma alert) ■ you have difficulty sleeping ■ you have a rapid heartbeat ■ you have tremors, nervousness or seizure ■ cough lasts for more than 1 week, containing ingredients reported or claimed to have a stimulant effect ■ avoid foods or beverages that contain caffeine ■ avoid dietary supplements product more frequently or take more than the recommended dose ■ have a history of high blood pressure or heart disease ■ take this cause death. ■ your risk of heart attack or stroke increases if you: ■ 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: ■ avoid dietary supplements ■ avoid foods or beverages that contain caffeine ■ avoid dietary supplements

Drug Facts (continued)

**LOG
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Manufactured by
DMD Pharmaceuticals
A Division of Dandy Consumer Products, Inc.
Indolepsville, IN 46060

INTENTIONAL ABUSE OF THIS PRODUCT
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Ephed Plus ^{EP 225}
**TEMPORARY RELIEF OF MILD INTERMITTENT
 ASTHMA SYMPTOMS**

NON-DROWSY

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TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS

HELPS RESTORE BREATHING AND LOOSENS PHLEGM

DMD Pharmaceuticals
24 TABLETS

Drug Facts (continued)
 Inactive ingredients: magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, silicon dioxide, sodium starch glycolate, stearic acid

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Drug Facts

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such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ that occurs with too much phlegm (mucus) ■ cough that lasts or is chronic condition ■ trouble urinating due to an enlarged prostate gland ■ cough ■ seizures ■ narrow angle glaucoma ■ a psychiatric or emotional ■ heart disease ■ high blood pressure ■ diabetes ■ thyroid disease ■ Ask a doctor before use if you have ■ ever been hospitalized for asthma before taking this product. ■ If your prescription drug contains an MAOI, ask a doctor or pharmacist 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.

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Drug Facts (continued)

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Ephed Plus
EP 225

Ephed Plus
EP 225
TEMPORARY RELIEF OF MILD INTERMITTENT
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Ephedrine Plus
NON-DROWSY
Ephedrine HCl 25 mg, Bronchodilator • Guaifenesin 200 mg, Expectorant
TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS
HELPS RESTORE BREATHING AND LOOSENS PHLEGM
DMD Pharmaceuticals
24 TABLETS

Manufactured by
DMD Pharmaceuticals
A Division of Dandy Consumer Products, Inc.
Indolepsville, IN 46060

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0 98443 24055 8

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Ephed Plus EP 225

TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS

NON-DROWSY

Ephed Plus EP 225

Ephedrine HCl 25 mg, Bronchodilator • Guaifenesin 200 mg, Expectorant

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HELPS RESTORE BREATHING AND LOOSENS PHEGM

24 TABLETS

DMD Pharmaceuticals

LOG BOOK ITEM

INTENTIONAL ABUSE OF THIS PRODUCT CAN BE HARMFUL OR FATAL

Manufactured by **DMD Pharmaceuticals**, A Division of Dandy Consumer Products, Inc. Indianapolis, IN 46260

0 98443 24055 8

Drug Facts (continued)

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

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EPHED PLUS
 ephedrine hydrochloride, guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65193-225
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EPHEDRINE HYDRO CHLORIDE (UNII: NLJ6390P1Z) (EPHEDRINE - UNII:GN83C131XS)	EPHEDRINE HYDROCHLORIDE	25 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65193-225-24	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	04/02/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/02/2019	

Labeler - Dickey Consumer Products DBA DMD (835974056)**Registrant** - Dickey Consumer Products DBA DMD (835974056)**Establishment**

Name	Address	ID/FEI	Business Operations
Ulratlab Laboratories, Inc.		151051757	manufacture(65193-225)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corp.		085752004	pack(65193-225)

Revised: 4/2019

Dickey Consumer Products DBA DMD