

**RED LABEL EPHEDRINE 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 12.5 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 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 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 foods 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: oral dose is 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

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

NO INK OR COAT

2458200-243

NO INK OR COAT

NO INK OR COAT

**Drug Facts** (continued)

**Active Ingredients (in each tablet)**  
 Ephedrine HCl, 12.5 mg  
 Guaifenesin, USP 200 mg

**Purposes**  
 Bronchodilator  
 Expectorant

**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 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 in adults and children 12 years of age and over; oral dose is 1 to 2 tablets every 4 hours as needed, do not take more than 12 tablets in 24 hours in children under 12 years of age; do not use 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.

**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.

**If pregnant or breast-feeding,** ask a health professional before use.

**Drug Facts** (continued)

# Ephedrine Plus

TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS

LOG BOOK ITEM

NO INK OR COAT

NO INK OR COAT

**Ephed Plus**

**RED LABEL**

# Ephedrine Plus

**EP 12.5**

Ephedrine HCl 12.5 mg, Bronchodilator • Guaifenesin 200 mg, Expectorant

**TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS**

**HELPS RESTORE BREATHING AND LOOSENS PHLEGM**

**DMD Pharmaceuticals**

**48 TABLETS**

**Ephedrine Plus**

**EP 12.5**

INTENTIONAL ABUSE OF THIS PRODUCT CAN BE HARMFUL OR FATAL.

Ma Retail by: **DMD Pharmaceuticals**  
 A Division of Dickey Corporation, Inc.  
 Nashville, TN 37203

0 98443 17044 2

**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](http://dmdpharm.com)

NO INK OR COAT

NO INK OR COAT



NO INK OR COAT

2458200-243

NO INK OR COAT

NO INK OR COAT

**Drug Facts** (continued)

**Active Ingredients (in each tablet)**  
 Ephedrine HCl, 12.5 mg  
 Guaifenesin, USP 200 mg  
 Expectorant

**Purposes**  
 Bronchodilator  
 Expectorant

**Use**  
 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 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 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 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.

**Directions** do not take more than directed in adults and children 12 years of age and over; oral dose is 1 to 2 tablets every 4 hours as needed, do not take more than 12 tablets in 24 hours in children under 12 years of age; do not use (68°F - 77°F) Tamper-evident: Each tablet is individually sealed.

**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.

**Drug Facts** (continued)

**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 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.

**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.

NO INK OR COAT

NO INK OR COAT

**Ephedrine Plus** EP 12.5  
 TEMPORARY RELIEF OF MILD INTERMITTENT  
 ASTHMA SYMPTOMS

LOG BOOK ITEM

**Ephed Plus** EP 12.5  
**RED LABEL**  
**Ephedrine Plus** EP 12.5  
 Ephedrine HCl 12.5 mg, Bronchodilator • Guaifenesin 200 mg, Expectorant  
 TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS  
 HELPS RESTORE BREATHING AND LOOSENS PHLEGM  
**DMD** Pharmaceuticals  
**48 TABLETS**

INTENTIONAL ABUSE OF THIS PRODUCT  
 CAN BE HARMFUL OR FATAL

Ma Retail by:  
**DMD Pharmaceuticals**  
 A Division of Dickey Corporation Products, Inc.  
 Nashville, TN 37203

0 98443 17044 2

NO INK OR COAT

NO INK OR COAT

**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](http://dmdpharm.com)



NO INK OR COAT

2458200-243



NO INK OR COAT

NO INK OR COAT

**Drug Facts** (continued)

**Active Ingredients (in each tablet)**  
 Ephedrine HCl, 12.5 mg  
 Guaifenesin, USP 200 mg  
 Expectorant

**Purposes**  
 Bronchodilator  
 Expectorant

**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.

**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 in adults and children 12 years of age and over; oral dose is 1 to 2 tablets every 4 hours as needed, do not take more than 12 tablets in 24 hours in children under 12 years of age; do not use 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.

**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.

**If pregnant or breast-feeding,** ask a health professional before use.

**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.

**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.

**Ephedrine Plus** EP 12.5

TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS

LOG BOOK ITEM

NO INK OR COAT

NO INK OR COAT

INTENTIONAL ABUSE OF THIS PRODUCT CAN BE HARMFUL OR FATAL

Ma Retail by: **DMD Pharmaceuticals**  
 A Division of Dickey Corporation, Inc.  
 Nashville, TN 37203

www.dmdpharm.com

**RED LABEL**

**Ephedrine Plus** EP 12.5

**Ephedrine Plus** EP 12.5

**TEMPORARY RELIEF OF MILD INTERMITTENT ASTHMA SYMPTOMS**

**HELPS RESTORE BREATHING AND LOOSENS PHLEGM**

Ephedrine HCl 12.5 mg, Bronchodilator • Guaifenesin 200 mg, Expectorant

**DMD Pharmaceuticals**

**48 TABLETS**



**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

NO INK OR COAT

NO INK OR COAT

ephedrine hydrochloride, guaifenesin tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:65193-125
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
EPHEDRINE HYDROCHLORIDE (UNII: NLJ6390P1Z) (EPHEDRINE - UNII:GN83C131XS)	EPHEDRINE HYDROCHLORIDE	12.5 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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

<b>Color</b>	white (snow white)	<b>Score</b>	no score
<b>Shape</b>	ROUND (EP125)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	EP125
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65193-125-48	48 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
Ultratab Laboratories, Inc.		151051757	manufacture(65193-125)

---

## Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corp.		085752004	pack(65193-125)

Revised: 4/2019

Dickey Consumer Products DBA DMD