

PSEUDO EPHED PLUS- pseudoephedrine 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): Pseudoephedrine HCl 30 mg, Guaifenesin 200 mg

Purposes - Nasal Decongestant, Expectorant

• temporarily relieves nasal congestion due to the common cold • promotes nasal and/or sinus drainage • temporarily relieves sinus congestion and pressure • helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Do not use: • 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: • heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland • persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema • a cough accompanied by excessive phlegm (mucus)

When using this product • do not use more than directed • intentional abuse of this product can be harmful or fatal

Stop use and ask a doctor if: • you get nervous dizzy or sleepless • cough lasts more than 7 days, comes back, or occurs with fever, rash or headache that lasts. These could be signs of a serious condition. • symptoms do not get better within 7 days or occur with a fever

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.

• adults and children 12 years of age and over: take 2 tablets every 4 to 6 hours; do not exceed 8 tablets in 24 hours • children under 12 years of age: ask a doctor

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

Drug Facts

Active ingredients (in each tablet)
 Guaifenesin 200 mg
 Pseudoephedrine HCl 30 mg
 Nasal Decongestant

Purposes
 Expectorant
 Nasal Decongestant

Uses ■ temporarily relieves nasal congestion due to the common cold ■ promotes nasal and/or sinus drainage ■ temporarily relieves sinus congestion and pressure ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings
 Do not use 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 ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ a cough accompanied by excessive phlegm (mucus)

When using this product ■ do not use more than directed ■ intentional abuse of this product can be harmful or fatal

Stop use and ask a doctor if ■ you get nervous, dizzy or sleepless ■ cough lasts more than 7 days, comes back, or occurs days or occur with a fever

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 ■ adults and children 12 years of age and over: take 2 tablets every 4 to 6 hours, do not exceed 8 tablets in 24 hours
 ■ children under 12: ask a doctor

Pseudo Ephed Plus
NASAL DECONGESTANT • EXPECTORANT

LOG BOOK ITEM

NON-DROWSY

Pseudo Ephed Plus
 OF EPHED DMD

Pseudoephedrine HCl 30 mg • Guaifenesin 200 mg

NASAL DECONGESTANT • EXPECTORANT

CONGESTION RELIEF

DMD Pharmaceuticals

24 TABLETS

Pseudo Ephed Plus
NASAL DECONGESTANT • EXPECTORANT

Drug Facts (continued)
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.
Inactive ingredients maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid

Questions? 1-800-795-2477 ■ visit us at: www.dmdpharm.com

Intentional Abuse of this Product Can Be Harmful or Fatal

Manufactured by
DMD Pharmaceuticals
 A Division of Dainippon Consumer Products, Inc.
 Noblesville, IN 46060 • dmdpharm.com

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PSEUDO EPHED PLUS			
pseudoephedrine hydrochloride, guaifenesin tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65193-325

Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DD19F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 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	no score	
Shape	ROUND (EP230)	Size	9mm	
Flavor		Imprint Code	EP230	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65193-325-24	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	03/15/2019	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	03/15/2019		

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(65193-325)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corp.		085752004	pack(65193-325)

