EPHED PLUS LIQUID- ephedrine guaifenes in liquid 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

Warnings

Purpose: Bronchodilator, Expectorant

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 to make coughs more productive

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

Directions do not take more than directed

adults and children 12 years of age and over: take 1

bottle every 4 hours as needed. Do not take more than

6 bottles in 24 hours children under 12 years of age:

do not use

Inactive ingredients Blue #1, Citric Acid, Filtered Water, Malic Acid, Natural and Artificial Flavors, Potassium Sorbate, Propylene Glycol, Sodium

Ephedrine HCI 25 mg, Bronchodilator Guaifenesin 400 mg, Expectorant



EPHED PLUS LIQUID

ephedrine guaifenesin liquid

Prod	net	Info	rma	tion
PIUU			1111117	

Product Type HUMAN OTC DRUG Item Code (Source) NDC:65193-180

Route of Administration ORAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength EPHEDRINE HYDRO CHLO RIDE (UNII: NLJ6390 P1Z) (EPHEDRINE UNII: GN8 3C131XS) EPHEDRINE HYDRO CHLO RIDE 25 mg in 60 mL guaifenesin (UNII: 495W7451VQ) (GUAIFENES IN - UNII: 495W7451VQ) guaifenesin

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		

SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
MALIC ACID (UNII: 817L1N4CKP)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q16 7 V3)	

Product Characteristics				
Color	purple (purple)	Score		
Shape		Size		
Flavor	grape	Imprint Code		
Contains				

ı	Packaging				
ı	# I	tem Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC	2:65193-180-57	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2017	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part341	11/10/2017		

Labeler - Dickey Consumer Products DBA DMD (835974056)

Registrant - Dickey Consumer Products DBA DMD (835974056)

Establishment				
Name	Address	ID/FEI	Business Operations	
Ultraseal Corporation		085752004	pack(65193-180)	

Establishment				
Name	Address	ID/FEI	Business Operations	
ULTRAtab Laboratories, Inc.		151051757	manufacture(65193-180)	

Revised: 4/2019 Dickey Consumer Products DBA DMD