

GUAIFENESIN 400- guaifenesin tablets 400 tablet
InvaTech Pharma Solutions LLC

Guaifenesin

cough, cold

Calcium sennosides 20% IH, Colloidal Silicon Di oxide USP/NF, Croscarmellose sodium USP/NF, Crospovidone [Kollidon] USP/NF, Dicalcium phosphate/ dibasic calcium phosphate [DIREC] USP/NF, Filmcoat AMB-51D0393632-Blue lake IH, Magnesium stearate. USP/NF, Microcrystalline cellulose (PH-102) USP/NF, Sodium lauryl sulfate USP/NF, Stearic acid powder USP/NF, Purified water

Sennosides Tablets USP, 25 mg Label

<u>GUAIFENESIN TABLETS USP, 400 MG</u>					
Each uncoated tablet contains: Guaifenesin USP, 400 mg					
Batch No.	:		Mfg. Date	:	
Shipper No.	:		Exp. Date	:	
Quantity	:	28,000 Tablets	Repack Before Date	:	
NDC No.	:	57631-012-00			
WARNING : KEEP OUT OF THE REACH OF CHILDREN					
Store At USP Controlled Room Temperature of 59° to 86° F (15° C to 30° C). Protect from Light, Moisture and Freezing.					HANDLE WITH CARE
This is a Bulk Shipment Intended for Further Processing Only. Contents Should Be Approved, Repackaged Immediately (9 Months From MFG. Date) and Labelled in strict conformance with The FD&C Act and Regulations There under.					“EB” Debossed
Manufactured By:			Manufactured For:		
ELYSIUM PHARMACEUTICALS LIMITED At & Post – Dabhaha, Tal.: Padra, Dist.: Vadodara, Gujarat – 391440, INDIA Manufacturer Code No.: GUJ/DRUGS/G/25/2258 Labeler Code #14803			INVATECH PHARMA SOLUTIONS LLC 40 C Cotters Lane, Suite # A, East Brunswick, NJ 08816 PH # 732-307-7926 FAX # 732-307-7931		
CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKING”					

GUAIFENESIN 400

guaifenesin tablets 400 tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57631-012
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
POVIDONE K30 (UNII: U725QWY32X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	EB
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57631-012-00	28000 in 1 BOX; Type 0: Not a Combination Product	01/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/13/2021	

Labeler - InvaTech Pharma Solutions LLC (078602180)

Registrant - Elysium Pharmaceuticals Ltd (915664486)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		915664486	analysis(57631-012) , manufacture(57631-012)

