

**GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE- guaifenesin and dextromethorphan hydrobromide tablet**  
**InvaTech Pharma Solutions LLC**

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**Guaifenesin, Dextromethorphan Hydrobromide Tablets**

FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING

KEEP OUT OF THE REACH OF CHILDREN

cough cold, allergic

KEEP OUT OF THE REACH OF CHILDREN, FOR FURTHER MANUFACTURING,  
PROCESSING OR REPACKING

Colloidal Silicon Di oxide USP/NF, Hypromellose 5 [ Hydroxy propyl methyl cellulose - E5] USP, Hypromellose 15 Hydroxy propyl methylcellulose E-15 USP, Magnesium stearate. USP/NF, Maltodextrin USP/NF, Microcrystalline cellulose (PH-102) USP/NF, Polyethylene glycol 400 USP/NF, Polyvinyl pyrrolidone (PVPK 30) USP, Sodium starch glycolate Type-A USP/NF, Stearic acid powder

|                                                                                                                                                                                                                                   |                                                                                                                       |                                                                                                                                                                |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>“ET16”<br/>DEBOSSSED</b>                                                                                                                                                                                                       | <b>GUAIFENESIN, DEXTROMETHORPHAN HYDROBROMIDE TABLETS</b>                                                             |                                                                                                                                                                |
|                                                                                                                                                                                                                                   | <u>Each Film Coated Tablet Contains:</u><br><b>Guaifenesin USP 400 mg and Dextromethorphan Hydrobromide USP 20 mg</b> |                                                                                                                                                                |
| Batch No. : _____                                                                                                                                                                                                                 |                                                                                                                       | Drum No. : _____                                                                                                                                               |
| Mfg. Date : _____                                                                                                                                                                                                                 |                                                                                                                       | Quantity : <b>26,500 Tablets</b>                                                                                                                               |
| Exp. Date : _____                                                                                                                                                                                                                 |                                                                                                                       | NDC No. : <b>57631-013-00</b>                                                                                                                                  |
| Repack Before Date: _____                                                                                                                                                                                                         |                                                                                                                       |                                                                                                                                                                |
| <b><u>WARNING: KEEP OUT OF THE REACH OF CHILDREN</u></b>                                                                                                                                                                          |                                                                                                                       |                                                                                                                                                                |
| STORE AT CONTROLLED ROOM TEMPERATURE OF 59° F TO 86° F<br>(15° C TO 30° C) PROTECT FROM LIGHT, MOISTURE AND FREEZING.                                                                                                             |                                                                                                                       |                                                                                                                                                                |
| THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD<br>BE APPROVED, REPACKAGED IMMEDIATELY (9 MONTHS FROM MFG. DATE) AND LABELED IN<br>STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS THEREUNDER. |                                                                                                                       |                                                                                                                                                                |
| Manufactured By :<br><b>ELYSIUM PHARMACEUTICALS LTD.</b><br>Manufacturer Code No.: G/25/1362<br>Labeler Code # 14803                                                                                                              |                                                                                                                       | Manufactured For :<br><b>INVATECH PHARMA SOLUTIONS LLC</b><br>40 C Cotters Lane, Suite # A,<br>East Brunswick, NJ 08816<br>PH # 732-307-7926 FAX # 732-307-793 |
| <b><u>CAUTION: “FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING”</u></b>                                                                                                                                                       |                                                                                                                       |                                                                                                                                                                |

SPM-917-01

**GUAIFENESIN AND DEXTROMETHORPHAN HYDROBROMIDE**  
guaifenesin and dextromethorphan hydrobromide tablet

| Product Information     |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:57631-013 |
| Route of Administration | ORAL           |                    |               |

| Active Ingredient/Active Moiety                                                              |                               |          |
|----------------------------------------------------------------------------------------------|-------------------------------|----------|
| Ingredient Name                                                                              | Basis of Strength             | Strength |
| <b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)                        | GUAIFENESIN                   | 400 mg   |
| <b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg    |

| Inactive Ingredients                                     |          |
|----------------------------------------------------------|----------|
| Ingredient Name                                          | Strength |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)             |          |
| <b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)                   |          |
| <b>POVIDONE K30</b> (UNII: U725QWY32X)                   |          |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)                  |          |
| <b>SODIUM STARCH GLYCOLATE TYPE A</b> (UNII: H8AV0SQX4D) |          |
| <b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)        |          |
| <b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)     |          |
| <b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)          |          |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                |          |

| Product Characteristics |       |              |          |
|-------------------------|-------|--------------|----------|
| Color                   | white | Score        | no score |
| Shape                   | OVAL  | Size         | 16mm     |
| Flavor                  |       | Imprint Code | ET16     |
| Contains                |       |              |          |

| Packaging |                  |                                                   |                      |                    |
|-----------|------------------|---------------------------------------------------|----------------------|--------------------|
| #         | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
| 1         | NDC:57631-013-10 | 26500 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)

| Establishment               |         |           |                                              |
|-----------------------------|---------|-----------|----------------------------------------------|
| Name                        | Address | ID/FEI    | Business Operations                          |
| Elysium Pharmaceuticals Ltd |         | 915664486 | manufacture(57631-013) , analysis(57631-013) |

Revised: 10/2025

InvaTech Pharma Solutions LLC