

**ACETAMINOPHEN AND DIPHENHYDRAMINE CITRATE- acetaminophen and  
diphenhydramine citrate tablet  
InvaTech Pharma Solutions LLC**

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**Acetaminophen and Diphenhydramine citrate**

KEEP OUT OF THE REACH OF CHILDREN

Analgesic and Antipyretic

FOR MANUFACTURING, PROCESSING OR REPACKING

KEEP OUT OF THE REACH OF CHILDREN,REMOVE SILICA GEL BAG BEFORE USE

Microcrystalline Cellulose, Polyethylene glycol, Polyvinyl pyrrolidinone, Pregelatinized Starch, Starch, Stearic Acid powder, colloidal Silicon Dioxide, talc, Hypromellose

FOR FURTHER MANUFACTURING, PROCESSING OR REPACKING

**PRINCIPAL DISPLAY PANEL**

<b>ACETAMINOPHEN AND DIPHENHYDRAMINE CITRATE TABLETS USP</b> <small>Each Film Coated Tablet Contains : Acetaminophen USP 500 mg and Diphenhydramine Citrate USP 38 mg</small>			
<b>Batch No.</b> : <b>Mfg. Date</b> : <b>Exp. Date</b> :	<b>Shipper No.</b> : <b>Quantity</b> : 30,000 Tablets <b>NDC No.</b> : 57631-010-00	<div>“S26” DEBOSSSED</div>	
<b>WARNING: KEEP OUT OF THE REACH OF CHILDREN</b>		Manufactured By :	
STORE AT USP CONTROLLED ROOM TEMPERATURE OF 59°F TO 86°F (15°C TO 30° C) PROTECT FROM LIGHT, MOISTURE AND FREEZING.		MANUFACTURER CODE No.: Guj/Drugs/G/1362 LABELER CODE # 14803	
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS THEREUNDER.		Manufactured For : <b>InvaTech Pharma Solutions LLC</b> 40 C Cotters Lane, Suite # A, East Brunswick, NJ 08816 PH # 732-307-7926 FAX # 732-307-7931	
<b>CAUTION : “FOR MANUFACTURING, PROCESSING OR REPACKING”</b>			

ACETAMINOPHEN AND DIPHENHYDRAMINE CITRATE			
acetaminophen and diphenhydramine citrate tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57631-010
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	500 mg
DIPHENHYDRAMINE CITRATE (UNII: 4OD433S209) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE CITRATE	38 mg
Inactive Ingredients			
Ingredient Name			Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I3O)			

<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>FD&amp;C BLUE NO. 2</b> (UNII: L06K8R7DQK)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	

### Product Characteristics

<b>Color</b>	blue	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	S26
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57631-010-00	30000 in 1 BOX; Type 0: Not a Combination Product	10/01/2025	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	10/01/2025	

**Labeler** - InvaTech Pharma Solutions LLC (078602180)

**Registrant** - Elysium Pharmaceutical Ltd (915664486)

### Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceutical Ltd		915664486	analysis(57631-010) , manufacture(57631-010)

Revised: 10/2025

InvaTech Pharma Solutions LLC