

FEXOFENADINE HYDROCHLORIDE- fexofenadine hydrochloride tablet
Granules India Limited

Fexofenadine HCl Tablets USP, 180 mg (Gel Caps)

Fexofenadine Hydrochloride Tablets, USP (Gel Caps) 180 mg

Each encapsulated coated tablet contains
 Fexofenadine Hydrochloride USP 180mg

Batch No. : XXXXXX	No. of Units : 40,000
Mfg.Dt. : YYYY/MM	Gross Wt. : 60.000 Kg
Exp.Dt. : YYYY/MM	Tare Wt. : 60.000 Kg
Mfg.Lic.No. : 37/RR/AP/2003/F/R	Net Wt. : 60.000 Kg
NDC No. : 62207-623-97	Drum No. : 600

Storage : Store at 20°C to 25°C (68°F to 77°F).

Caution : For repacking only.

Country of Origin: INDIA



⑉189038320000000004



⑉1)50362207623976(17)231102(10)??????

13726

FEXOFENADINE HYDROCHLORIDE

fexofenadine hydrochloride tablet

Product Information

Product Type	BULK INGREDIENT	Item Code (Source)	NDC:62207-623
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEXOFENADINE HYDROCHLORIDE (UNII: 2S068B75ZU) (FEXOFENADINE - UNII:E6582LOH6V)	FEXOFENADINE HYDROCHLORIDE	180 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
HYPROMELLOSE 2910 (3 MPA.S) (UNII: 0VUT3PMY82)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
AMMONIA (UNII: 5138Q19F1X)	
GELATIN (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE (90000 WAMW) (UNII: UKE75GEA7F)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	gray (White band in the middle)	Score	no score
Shape	OVAL (capsule shaped tablet)	Size	20mm
Flavor		Imprint Code	G18
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62207-623-97	40000 in 1 DRUM	11/27/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		11/27/2023	

Labeler - Granules India Limited (915000087)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	manufacture(62207-623)

Revised: 12/2023

Granules India Limited