

FEBUXOSTAT- febuxostat tablet
Zydus Lifesciences Limited

Febuxostat Tablets

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Febuxostat Tablets, 40 mg – 30's count

NDC- 70771-1552-3



Febuxostat Tablets, 80 mg – 30's count

NDC- 70771-1553-3



FEBUXOSTAT

febuxostat tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1552
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FEBUXOSTAT (UNII: 101V0R1N2E) (FEBUXOSTAT - UNII:101V0R1N2E)	FEBUXOSTAT	40 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	Score	no score
Shape	OVAL (OVAL)	Size	13mm
Flavor		Imprint Code	401

Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1552-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
2	NDC:70771-1552-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
3	NDC:70771-1552-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
4	NDC:70771-1552-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
5	NDC:70771-1552-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
6	NDC:70771-1552-4	10 in 1 CARTON	03/31/2023	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA205443	03/31/2023	

FEBUXOSTAT			
febuxostat tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:70771-1553
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
FEBUXOSTAT (UNII: 101V0R1N2E) (FEBUXOSTAT - UNII:101V0R1N2E)		FEBUXOSTAT	80 mg
Inactive Ingredients			
Ingredient Name			Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			

POVIDONE (UNII: FZ989GH94E)				
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	WHITE (WHITE TO OFF-WHITE)		Score	no score
Shape	ROUND (ROUND)		Size	12mm
Flavor			Imprint Code	402
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1553-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
2	NDC:70771-1553-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
3	NDC:70771-1553-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
4	NDC:70771-1553-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
5	NDC:70771-1553-0	1000 in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2023	
6	NDC:70771-1553-4	10 in 1 CARTON	03/31/2023	
6		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA205443	03/31/2023	

Labeler - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(70771-1552, 70771-1553) , MANUFACTURE(70771-1552, 70771-1553)

Revised: 10/2023

Zydus Lifesciences Limited