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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
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: 3WQ0SDW1A)	
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)