LEVOFLOXACIN- levofloxacin tablet, film coated
Zydus Lifesciences Limited

LEVOFLOXACIN TABLETS

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 65841-691-18 in bottle of 50 tablets

Levofloxacin Tablets USP, 250 mg

Rx only

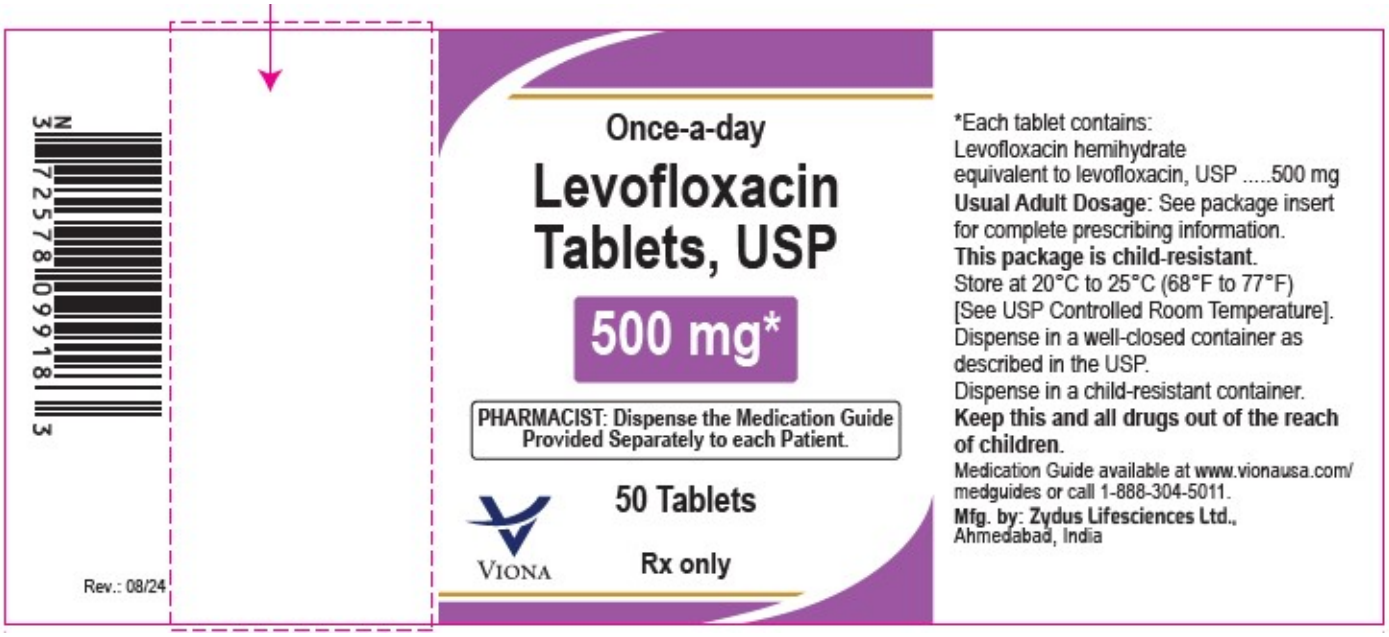
50 tablets

NDC 65841-692-18 in bottle of 50 tablets

Levofloxacin Tablets USP, 500 mg

Rx only

50 tablets



NDC 65841-693-06 in bottle of 30 tablets

Levofloxacin Tablets USP, 750 mg

Rx only

30 tablets

LEVOFLOXACIN

levofloxacin tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-691

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOFLOXACIN (UNII: 6GNT3Y5LMF) (LEVOFLOXACIN ANHYDROUS - UNII:RIX4E89Y14)	LEVOFLOXACIN ANHYDROUS	250 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics			
Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (MODIFIED CAPSULE)	**Size**	15mm
Flavor		**Imprint Code**	ZC55
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:65841-691-18	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	
2	NDC:65841-691-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	
3	NDC:65841-691-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077652	11/10/2012	

LEVOFLOXACIN

levofloxacin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-692
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOFLOXACIN (UNII: 6GNT3Y5LMF) (LEVOFLOXACIN ANHYDROUS - UNII:RIX4E89Y14)	LEVOFLOXACIN ANHYDROUS	500 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (MODIFIED CAPSULE)	**Size**	19mm
Flavor		**Imprint Code**	ZC56
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-692-18	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	
2	NDC:65841-692-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	
3	NDC:65841-692-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	
4	NDC:65841-692-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077652	11/10/2010	

LEVOFLOXACIN

levofloxacin tablet, film coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:65841-693
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOFLOXACIN (UNII: 6GNT3Y5LMF) (LEVOFLOXACIN ANHYDROUS - UNII:RIX4E89Y14)	LEVOFLOXACIN ANHYDROUS	750 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF-WHITE)	**Score**	no score
Shape	CAPSULE (MODIFIED CAPSULE)	**Size**	22mm
Flavor		**Imprint Code**	ZC57
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-693-18	50 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	
2	NDC:65841-693-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	
3	NDC:65841-693-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/10/2012	
4	NDC:65841-693-92	20 in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2022	
5	NDC:65841-693-06	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077652	11/10/2012	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		918596198	ANALYSIS(65841-691, 65841-692, 65841-693) , MANUFACTURE(65841-691, 65841-692, 65841-693)

Revised: 8/2024 Zydus Lifesciences Limited