

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

3 N
7 2 5 7 8 0 9 9 1 8 1
3

Rev.: 08/24

Once-a-day
**Levofloxacin
Tablets, USP**

500 mg*

PHARMACIST: Dispense the Medication Guide
Provided Separately to each Patient.

 **50 Tablets**
Rx only

*Each tablet contains:
Levofloxacin hemihydrate
equivalent to levofloxacin, USP500 mg
Usual Adult Dosage: See package insert
for complete prescribing information.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature].
Dispense in a well-closed container as
described in the USP.
Dispense in a child-resistant container.
**Keep this and all drugs out of the reach
of children.**
Medication Guide available at [www.vionausa.com/
medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.
**Mfg. by: Zydus Lifesciences Ltd.,
Ahmedabad, India**

NDC 65841-693-06 in bottle of 30 tablets

Levofloxacin Tablets USP, 750 mg

Rx only

30 tablets

3 N
7 2 5 7 8 1 1 0 0 0 6 1
3

Rev.: 08/24

Once-a-day
**Levofloxacin
Tablets, USP**

750 mg*

PHARMACIST: Dispense the Medication Guide
Provided Separately to each Patient.

 **30 Tablets**
Rx only

*Each tablet contains:
Levofloxacin hemihydrate
equivalent to levofloxacin, USP750 mg
Usual Adult Dosage: See package insert
for complete prescribing information.
This package is child-resistant.
Store at 20°C to 25°C (68°F to 77°F)
[See USP Controlled Room Temperature].
Dispense in a well-closed container as
described in the USP.
Dispense in a child-resistant container.
**Keep this and all drugs out of the reach
of children.**
Medication Guide available at [www.vionausa.com/
medguides](http://www.vionausa.com/medguides) or call 1-888-304-5011.
**Mfg. by: Zydus Lifesciences Ltd.,
Ahmedabad, India**

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
CROSPVIDONE (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
CROSPVIDONE (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
CROSPVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
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