LAMOTRIGINE- lamotirigine tablet, extended release
Zydus Lifesciences Limited

LAMOTRIGINE Extended-release Tablets

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 70771-1514-3

Lamotrigine extended-release tablets, 25 mg

Rx only

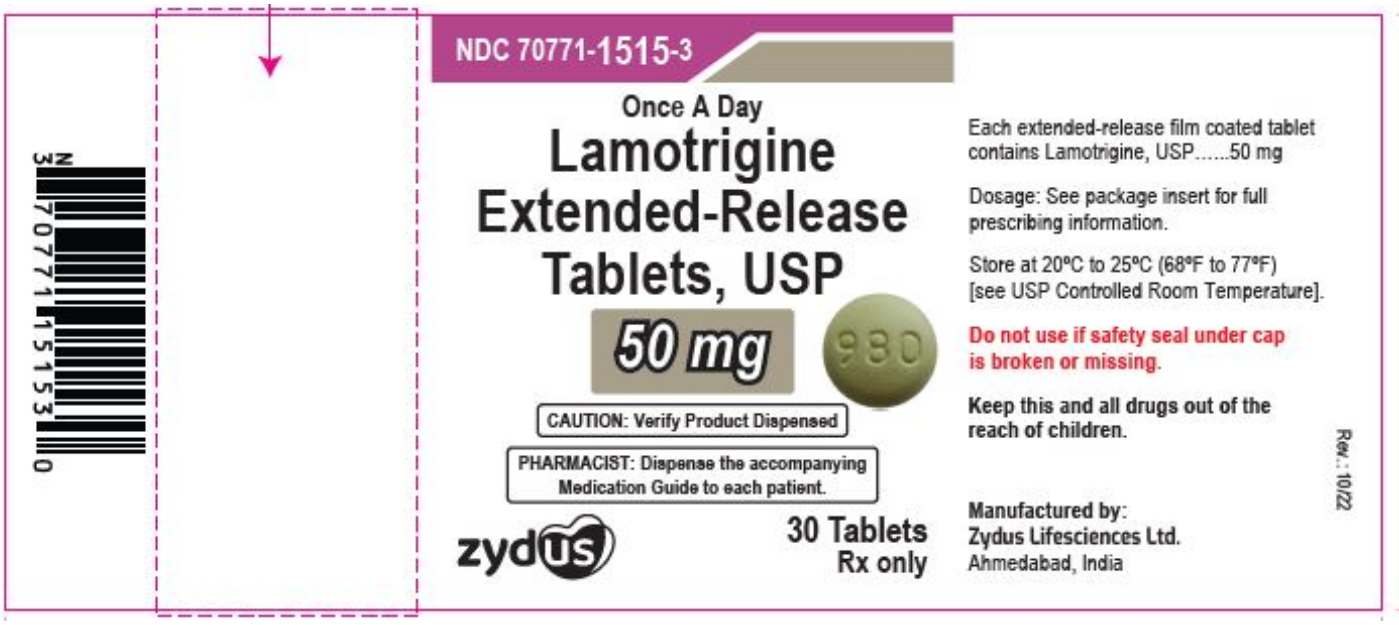
30 tablets

NDC 70771-1515-3

Lamotrigine extended-release tablets, 50 mg

Rx only

30 tablets

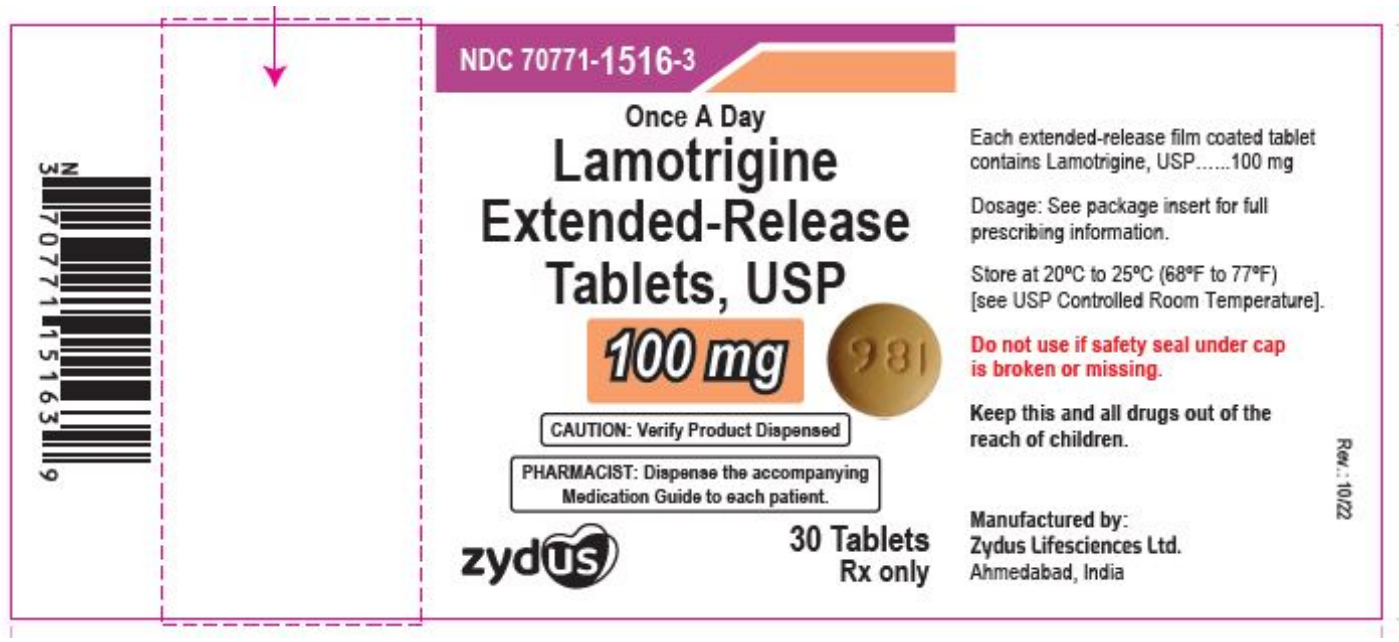


NDC 70771-1516-3

Lamotrigine extended-release tablets, 100 mg

Rx only

30 tablets



NDC 70771-1517-3

Lamotrigine extended-release tablets, 200 mg

Rx only

30 tablets

NDC 70771-1518-3

Lamotrigine extended-release tablets, 250 mg

Rx only

30 tablets

NDC 70771-1519-3

Lamotrigine extended-release tablets, 300 mg

Rx only

30 tablets

LAMOTRIGINE

lamotirigine tablet, extended release

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1514
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LAMOTRIGINE (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	YELLOW (LIGHT YELLOW TO YELLOW)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	979
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1514-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
2	NDC:70771-1514-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
3	NDC:70771-1514-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
4	NDC:70771-1514-4	10 in 1 CARTON	05/14/2020	
4	NDC:70771-1514-2	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	ANDA207763	05/14/2020	

LAMOTRIGINE

lamotirigine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1515
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	GREEN (LIGHT GREEN TO GREEN)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	9mm
Flavor		**Imprint Code**	980
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1515-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
2	NDC:70771-1515-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
3	NDC:70771-1515-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
4	NDC:70771-1515-4	10 in 1 CARTON	05/14/2020	
4	NDC:70771-1515-2	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	ANDA207763	05/14/2020	

LAMOTRIGINE

lamotirigine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1516
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	ORANGE (LIGHT ORANGE TO ORANGE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	981
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:70771-1516-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
2	NDC:70771-1516-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
3	NDC:70771-1516-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
4	NDC:70771-1516-4	10 in 1 CARTON	05/14/2020	
4	NDC:70771-1516-2	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	ANDA207763	05/14/2020	

LAMOTRIGINE

lamotirigine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1517
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	BLUE (LIGHT BLUE TO BLUE)	**Score**	no score
Shape	ROUND (ROUND)	**Size**	10mm
Flavor		**Imprint Code**	982
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1517-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
2	NDC:70771-1517-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
3	NDC:70771-1517-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
4	NDC:70771-1517-4	10 in 1 CARTON	05/14/2020	
4	NDC:70771-1517-2	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	ANDA207763	05/14/2020	

LAMOTRIGINE

lamotirigine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1518
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	250 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
CARMINIC ACID (UNII: CID8Z8N95N)	

Product Characteristics

Color	PURPLE (LIGHT PURPLE TO PURPLE)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	16mm
Flavor		**Imprint Code**	983
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1518-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
2	NDC:70771-	90 in 1 BOTTLE; Type 0: Not a Combination	05/14/2020	

2	1518-9	Product	05/14/2020	
3	NDC:70771-1518-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
4	NDC:70771-1518-4	10 in 1 CARTON	05/14/2020	
4	NDC:70771-1518-2	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	ANDA207763	05/14/2020	

LAMOTRIGINE

lamotirigine tablet, extended release

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:70771-1519
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	300 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	GRAY (LIGHT GRAY TO GRAY)	**Score**	no score
Shape	OVAL (OVAL)	**Size**	16mm

Flavor		**Imprint Code**	984
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70771-1519-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
2	NDC:70771-1519-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
3	NDC:70771-1519-5	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/14/2020	
4	NDC:70771-1519-4	10 in 1 CARTON	05/14/2020	
4	NDC:70771-1519-2	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	ANDA207763	05/14/2020	

Labeler - Zydus Lifesciences Limited (918596198)

Registrant - Zydus Lifesciences Limited (918596198)

Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences Limited		863362789	ANALYSIS(70771-1514, 70771-1515, 70771-1516, 70771-1517, 70771-1518, 70771-1519) , MANUFACTURE(70771-1514, 70771-1515, 70771-1516, 70771-1517, 70771-1518, 70771-1519)

Revised: 10/2023 Zydus Lifesciences Limited