

**LAMOTRIGINE- lamotrigine tablet, extended release**  
**Cadila Healthcare Limited**

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**LAMOTRIGINE Extended-release Tablets**

**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



Over Coding Template

No Varnished Area (Do Not Print)  
(18 x 41 mm)

**NDC 70771-1515-3**

Once A Day  
**Lamotrigine**  
**Extended-Release**  
**Tablets, USP**

**50 mg**

**CAUTION: Verify Product Dispensed**

**PHARMACIST: Dispense the accompanying Medication Guide to each patient.**

**zydus** pharmaceuticals

**30 Tablets**  
**Rx only**

Each extended-release film coated tablet contains Lamotrigine, USP.....50 mg

Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F)  
[see USP Controlled Room Temperature].

**Do not use if safety seal under cap is broken or missing.**

Keep this and all drugs out of the reach of children.

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev: 04/20

95 mm

41 mm

Colours: PANTONE 2597 C PANTONE 314 C PANTONE 7536 C

Die Cut Line (Do Not Print) No Varnished Area (Do Not Print)

NDC 70771-1516-3

Lamotrigine extended-release tablets, 100 mg

Rx only

30 tablets



Over Coding Template

No Varnished Area (Do Not Print)  
(18 x 41 mm)

NDC 70771-1516-3

Once A Day  
**Lamotrigine**  
**Extended-Release**  
**Tablets, USP**  
**100 mg**

Each extended-release film coated tablet contains Lamotrigine, USP.....100 mg  
Dosage: See package insert for full prescribing information.  
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].  
**Do not use if safety seal under cap is broken or missing.**  
Keep this and all drugs out of the reach of children.

CAUTION: Verify Product Dispensed  
PHARMACIST: Dispense the accompanying Medication Guide to each patient.

zydus  
30 Tablets  
Rx only

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev. 04/20

95 mm

41 mm

Colours: PANTONE 2597 C PANTONE 314 C PANTONE 1565 C CMYK

Die Cut Line (Do Not Print)

No Varnished Area (Do Not Print)

NDC 70771-1517-3

Lamotrigine extended-release tablets, 200 mg

Rx only

30 tablets



Over Coding Template

No Varnished Area (Do Not Print)  
(18 x 41 mm)

NDC 70771-1517-3

Once A Day  
**Lamotrigine**  
**Extended-Release**  
**Tablets, USP**  
**200 mg**

Each extended-release film coated tablet contains Lamotrigine, USP .....200 mg

Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

**Do not use if safety seal under cap is broken or missing.**

Keep this and all drugs out of the reach of children.

CAUTION: Verify Product Dispensed

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

30 Tablets  
Rx only

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rev: 04/20

95 mm

41 mm

Colours: PANTONE 2597 C PANTONE 314 C PANTONE 7546 C CMYK

Die Cut Line (Do Not Print) No Varnished Area (Do Not Print)

NDC 70771-1518-3

Lamotrigine extended-release tablets, 250 mg

Rx only

30 tablets



Over Coding Template

No Varnished Area (Do Not Print)  
(18 x 41 mm)

NDC 70771-1518-3

Once A Day  
**Lamotrigine**  
**Extended-Release**  
**Tablets, USP**

**250 mg** 983

CAUTION: Verify Product Dispensed

PHARMACIST: Dispense the accompanying Medication Guide to each patient.

**zydus** pharmaceuticals

**30 Tablets**  
**Rx only**

Each extended-release film coated tablet contains Lamotrigine, USP.....250 mg

Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

**Do not use if safety seal under cap is broken or missing.**

Keep this and all drugs out of the reach of children.

Manufactured by:  
Cadila Healthcare Ltd.  
Ahmedabad, India

Rw: 04/20

95 mm

41 mm

Colours: PANTONE 2597 C PANTONE 314 C PANTONE 513 C CMYK

Die Cut Line (Do Not Print) No Varnished Area (Do Not Print)

NDC 70771-1519-3

Lamotrigine extended-release tablets, 300 mg

Rx only

30 tablets



Colours:  PANTONE 2597 C  PANTONE 314 C  PANTONE Cool Gray 2 C  CMYK

 Die Cut Line (Do Not Print)  No Varnished Area (Do Not Print)

## LAMOTRIGINE

lamotrigine tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1514
<b>Route of Administration</b>	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)	

<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A</b> (UNII: NX76LV5T8J)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0K00R)	

### Product Characteristics

<b>Color</b>	YELLOW (LIGHT YELLOW TO YELLOW)	<b>Score</b>	no score
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	979
<b>Contains</b>			

### 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

lamotrigine tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1515
<b>Route of Administration</b>	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
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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 - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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

lamotrigine 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 - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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

lamotrigine 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)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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**

lamotrigine tablet, extended release

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1518
<b>Route of Administration</b>	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)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
CARMINIC ACID (UNII: CID8Z8N95N)	

**Product Characteristics**

<b>Color</b>	PURPLE (LIGHT PURPLE TO PURPLE)	<b>Score</b>	no score
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	983
<b>Contains</b>			

**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:70771-1518-9	90 in 1 BOTTLE; Type 0: Not a Combination 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

lamotrigine tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:70771-1519
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
LAMOTRIGINE (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	300 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

## Product Characteristics

<b>Color</b>	GRAY (LIGHT GRAY TO GRAY)	<b>Score</b>	no score
<b>Shape</b>	OVAL (OVAL)	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	984
<b>Contains</b>			

## 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** - Cadila Healthcare Limited (918596198)

**Registrant** - Cadila Healthcare Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Cadila Healthcare 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: 5/2020

Cadila Healthcare Limited