

LAMOTRIGINE- lamotrigine tablet
LAMOTRIGINE- lamotrigine tablet, chewable
Cadila Healthcare Limited

LAMOTRIGINE TABLETS and LAMOTRIGINE TABLETS (CHEWABLE, DISPERSIBLE).

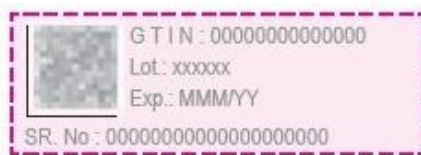
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Lamotrigine Tablets (Chewable, Dispersible), 5 mg

NDC 65841-689-01 in bottle of 100 tablets

100 tablets

Rx only



Over Coding Template

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

NDC 65841-689-01

**Lamotrigine Tablets
for Oral Suspension, USP
(Chewable, Dispersible Tablets)***

5 mg

CAUTION: Verify Product Dispensed

Dispense the accompanying Medication Guide to each patient.

**100 Tablets
Rx only**

Each tablet contains: Lamotrigine, USP5 mg
Phenylketonurics: Phenylalanine is a component of aspartame. Each lamotrigine tablet for oral suspension, 5 mg contains 0.7 mg of phenylalanine.
*Tablets may be swallowed whole, chewed, or dispensed in water or diluted fruit juice.
See package insert for Dosage and Administration.
Usual Dosage: See package insert for complete prescribing information.
Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room Temperature].
Do not accept if printed seal under cap is missing or broken.
Dispense in a tight, light-resistant container.
KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.
The drug product complies with Organic Impurities Procedure 2.
Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India

Rev. 08/18
GADUR/CH/486

Lamotrigine Tablets (Chewable, Dispersible), 5 mg

Lamotrigine Tablets (Chewable, Dispersible), 25 mg

NDC 65841-690-01 in bottle of 100 tablets

100 tablets

Rx only

GTIN : 00000000000000
 Lot : xxxxxx
 Exp. : MMM/YY
 SR. No : 00000000000000000000

Over Coding Template

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

NDC 65841-690-01

Lamotrigine Tablets
for Oral Suspension, USP
(Chewable, Dispersible Tablets)*

25 mg

CAUTION: Verify Product Dispensed

Dispense the accompanying Medication Guide to each patient.

100 Tablets
Rx only

Each tablet contains: Lamotrigine, USP25 mg
Phenylketonurics: Phenylalanine is a component of aspartame. Each lamotrigine tablet for oral suspension, 25 mg contains 0.7 mg of phenylalanine.
 *Tablets may be swallowed whole, chewed, or dispensed in water or diluted fruit juice.
 See package insert for Dosage and Administration.
Usual Dosage: See package insert for complete prescribing information.
 Store at 20° to 25°C (68° to 77°F)
 [See USP Controlled Room Temperature].
Do not accept if printed seal under cap is missing or broken.
 Dispense in a tight, light-resistant container.
KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.
 The drug product complies with Organic Impurities Procedure 2.
 Manufactured by: Cadila Healthcare Ltd. Ahmedabad, India

Rev: 08/18

Lamotrigine Tablets (Chewable, Dispersible), 25 mg

Lamotrigine Tablets USP, 25 mg
 NDC 65841-682-01 in bottle of 100 tablets
 100 tablets
 Rx only

NDC 65841-682-01

Lamotrigine Tablets, USP

25 mg

CAUTION: Verify Product Dispensed

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

100 TABLETS
Rx only

Each tablet contains:
 Lamotrigine, USP.....25 mg
Usual Dosage: See package insert for complete prescribing information.
 Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature] in a dry place.
Do not accept if printed seal under cap is missing or broken.
 Dispense in a tight, light-resistant container as defined in the USP.
KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.
 Manufactured by:
 Cadila Healthcare Ltd.
 India

Rev: 08/18

Lamotrigine Tablets USP, 25 mg

Lamotrigine Tablets USP, 50 mg
NDC 65841-683-01 in bottle of 100 tablets
100 tablets
Rx only

NDC 65841-683-01

Lamotrigine
Tablets, USP

50 mg

CAUTION: Verify Product Dispensed

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

zydus
pharmaceuticals

100 TABLETS
Rx only

Each tablet contains:
Lamotrigine, USP.....50 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature] in a dry place.

Do not accept if printed seal under cap is missing or broken.

Dispense in a tight, light-resistant container as defined in the USP.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
India

Rev.: 06/18

Lamotrigine Tablets USP, 50 mg

Lamotrigine Tablets USP, 100 mg
NDC 65841-684-01 in bottle of 100 tablets
100 tablets
Rx only

NDC 65841-684-01

Lamotrigine
Tablets, USP

100 mg

CAUTION: Verify Product Dispensed

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

zydus
pharmaceuticals

100 TABLETS
Rx only

Each tablet contains:
Lamotrigine, USP.....100 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature] in a dry place.

Do not accept if printed seal under cap is missing or broken.

Dispense in a tight, light-resistant container as defined in the USP.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
India

Rev.: 06/18

Lamotrigine Tablets USP, 100 mg

Lamotrigine Tablets USP, 150 mg

NDC 65841-685-14 in bottle of 60 tablets

60 tablets

Rx only

NDC 65841-685-14

**Lamotrigine
Tablets, USP**

150 mg

CAUTION: Verify Product Dispensed

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

60 TABLETS
Rx only

zydus
pharmaceuticals

Each tablet contains:
Lamotrigine, USP.....150 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature] in a dry place.

Do not accept if printed seal under cap is missing or broken.

Dispense in a tight, light-resistant container as defined in the USP.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
India

Rev: 06/18

Lamotrigine Tablets USP, 150 mg

Lamotrigine Tablets USP, 200 mg

NDC 65841-686-14 in bottle of 60 tablets

60 tablets

Rx only

NDC 65841-686-14

**Lamotrigine
Tablets, USP**

200 mg

CAUTION: Verify Product Dispensed

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

60 TABLETS
Rx only

zydus
pharmaceuticals

Each tablet contains:
Lamotrigine, USP.....200 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature] in a dry place.

Do not accept if printed seal under cap is missing or broken.

Dispense in a tight, light-resistant container as defined in the USP.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Manufactured by:
Cadila Healthcare Ltd.
India

Rev: 06/18

Lamotrigine Tablets USP, 200 mg

Lamotrigine Tablets USP, 250 mg
 NDC 65841-687-05 in bottle of 500 tablets
 500 tablets
 Rx only

NDC 65841-687-05

Lamotrigine Tablets, USP

250 mg

CAUTION: Verify Product Dispensed

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

zydus pharmaceuticals

500 TABLETS
Rx only

Manufactured by:
Cadila Healthcare Ltd.
India

Rev.: 06/18

Each tablet contains:
Lamotrigine, USP.....250 mg

Usual Dosage: See package insert for complete prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature] in a dry place.

Do not accept if printed seal under cap is missing or broken.

Dispense in a tight, light-resistant container as defined in the USP.

KEEP THIS AND ALL THE DRUGS OUT OF THE REACH OF CHILDREN.

Lamotrigine Tablets USP, 250 mg

LAMOTRIGINE			
lamotrigine tablet			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-682
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
LAMOTRIGINE (UNII: U3H27498 KS) (LAMOTRIGINE - UNII:U3H27498 KS)		LAMOTRIGINE	25 mg
Inactive Ingredients			
Ingredient Name			Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
POVIDONE (UNII: FZ989GH94E)			
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D6 1U)			

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	6mm
Flavor		Imprint Code	ZC;79
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-682-11	25 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
2	NDC:65841-682-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
3	NDC:65841-682-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
4	NDC:65841-682-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
5	NDC:65841-682-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077633	01/27/2009	

LAMOTRIGINE

lamotrigine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-683
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
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	7mm
Flavor		Imprint Code	ZC;90
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-683-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
2	NDC:65841-683-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
3	NDC:65841-683-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
4	NDC:65841-683-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077633	01/27/2009	

LAMOTRIGINE

lamotrigine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-684
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
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	10mm
Flavor		Imprint Code	ZC;80
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-684-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
2	NDC:65841-684-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
3	NDC:65841-684-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
4	NDC:65841-684-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077633	01/27/2009	

LAMOTRIGINE

lamotrigine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-685
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	150 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	11mm
Flavor		Imprint Code	ZC;81
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-685-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	

2	NDC:65841-685-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
3	NDC:65841-685-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077633	01/27/2009	

LAMOTRIGINE

lamotrigine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-686
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
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	13mm
Flavor		Imprint Code	ZC;82
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-686-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
2	NDC:65841-686-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
3	NDC:65841-686-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077633	01/27/2009	

LAMOTRIGINE

lamotrigine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-687
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
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
POVIDONE (UNII: FZ989GH94E)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	13mm
Flavor		Imprint Code	ZC;91
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-687-14	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
2	NDC:65841-687-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	
3	NDC:65841-687-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/27/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA077633	01/27/2009	

LAMOTRIGINE

lamotrigine tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-689
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (UNII: U3H27498 KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
BLACK CURRANT (UNII: 9755T40D11)	

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	10mm
Flavor	BERRY (Black Current)	Imprint Code	Z;13
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-689-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2009	
2	NDC:65841-689-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2009	
3	NDC:65841-689-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078009	01/23/2009	

LAMOTRIGINE

lamotrigine tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:65841-690
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
ASPARTAME (UNII: Z0H242BBR1)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
BLACK CURRANT (UNII: 9755T40D11)	

Product Characteristics

Color	WHITE (WHITE TO OFF- WHITE)	Score	no score
Shape	ROUND (ROUND)	Size	10mm
Flavor	BERRY (Black Current)	Imprint Code	Z;12
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65841-690-16	90 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2009	
2	NDC:65841-690-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2009	
3	NDC:65841-690-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	01/23/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078009	01/23/2009	

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

Name	Address	ID/FEI	Business Operations
Cadila Healthcare Limited		918596198	ANALYSIS(65841-682, 65841-683, 65841-684, 65841-685, 65841-686, 65841-687, 65841-689, 65841-690) , MANUFACTURE(65841-682, 65841-683, 65841-684, 65841-685, 65841-686, 65841-687, 65841-689, 65841-690)

Revised: 8/2020

Cadila Healthcare Limited