

**LAMOTRIGINE- lamotrigine tablet**  
**LAMOTRIGINE- lamotrigine tablet, chewable**  
**Zydus Lifesciences Limited**

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**LAMOTRIGINE TABLETS and LAMOTRIGINE TABLETS (CHEWABLE, DISPERSIBLE).**

**SPL MEDGUIDE**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

Lamotrigine Tablets (Chewable, Dispersible), 5 mg

NDC 65841-689-01 in bottle of 100 tablets

100 tablets

Rx only



**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

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.

**zydus** **100 Tablets  
Rx only**

Each tablet contains: Lamotrigine, USP .....25 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°C to 25°C (68°F 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 drugs out of the reach of children.**  
The drug product complies with Organic Impurities Procedure 2.  
Manufactured by: Zydus Lifesciences Ltd. Ahmedabad, India

Rev: 10/22

**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.**

**zydus** **100 Tablets  
Rx only**

Each tablet contains:  
Lamotrigine, USP.....25 mg  
**Usual Dosage:** See package insert for complete prescribing information.  
Store at 20°C to 25°C (68°F 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 drugs out of the reach of children.**  
Manufactured by:  
Zydus Lifesciences Ltd.  
India

Rev: 10/22

**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

100 Tablets  
Rx only

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

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20°C to 25°C (68°F 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 drugs out of the reach of children.

Manufactured by:  
Zydus Lifesciences Ltd.  
India

Rev.: 10/22

**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

100 Tablets  
Rx only

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

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20°C to 25°C (68°F 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 drugs out of the reach of children.

Manufactured by:  
Zydus Lifesciences Ltd.  
India

Rev.: 10/22

**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.

zydUS

60 Tablets  
Rx only

Manufactured by:  
Zydus Lifesciences Ltd.  
India

Rev: 10/22

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

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20°C to 25°C (68°F 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 drugs out of the reach of children.**

**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.

zydUS

60 Tablets  
Rx only

Manufactured by:  
Zydus Lifesciences Ltd.  
India

Rev: 10/22

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

**Usual Dosage:** See package insert for complete prescribing information.

Store at 20°C to 25°C (68°F 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 drugs out of the reach of children.**

**Lamotrigine Tablets USP, 200 mg**

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

**Lamotrigine Tablets USP, 250 mg**

<b>LAMOTRIGINE</b>			
lamotrigine tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-682
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
LAMOTRIGINE (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)		LAMOTRIGINE	25 mg
<b>Inactive Ingredients</b>			
<b>Ingredient Name</b>			<b>Strength</b>
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

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

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-683
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LAMOTRIGINE</b> (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	50 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6130)	

<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

### Product Characteristics

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

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-684
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LAMOTRIGINE</b> (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	100 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	

<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

Product Characteristics			
<b>Color</b>	WHITE (WHITE TO OFF- WHITE)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND (ROUND)	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	ZC;80
<b>Contains</b>			

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

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
<b>LAMOTRIGINE</b> (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	150 mg

Inactive Ingredients	
Ingredient Name	Strength
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	



<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	

### Product Characteristics

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

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-686
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LAMOTRIGINE</b> (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	200 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>LACTOSE MONOHYDRATE</b> (UNII: EWQ57Q8I5X)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)

### Product Characteristics

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

### 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-687
<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
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

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

## 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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>LAMOTRIGINE</b> (UNII: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	5 mg

### Inactive Ingredients

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

## Product Characteristics

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

## 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:65841-690
<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
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

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

### 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** - Zydus Lifesciences Limited (918596198)

**Registrant** - Zydus Lifesciences Limited (918596198)

### Establishment

Name	Address	ID/FEI	Business Operations
Zydus Lifesciences 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: 11/2024

Zydus Lifesciences Limited