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

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

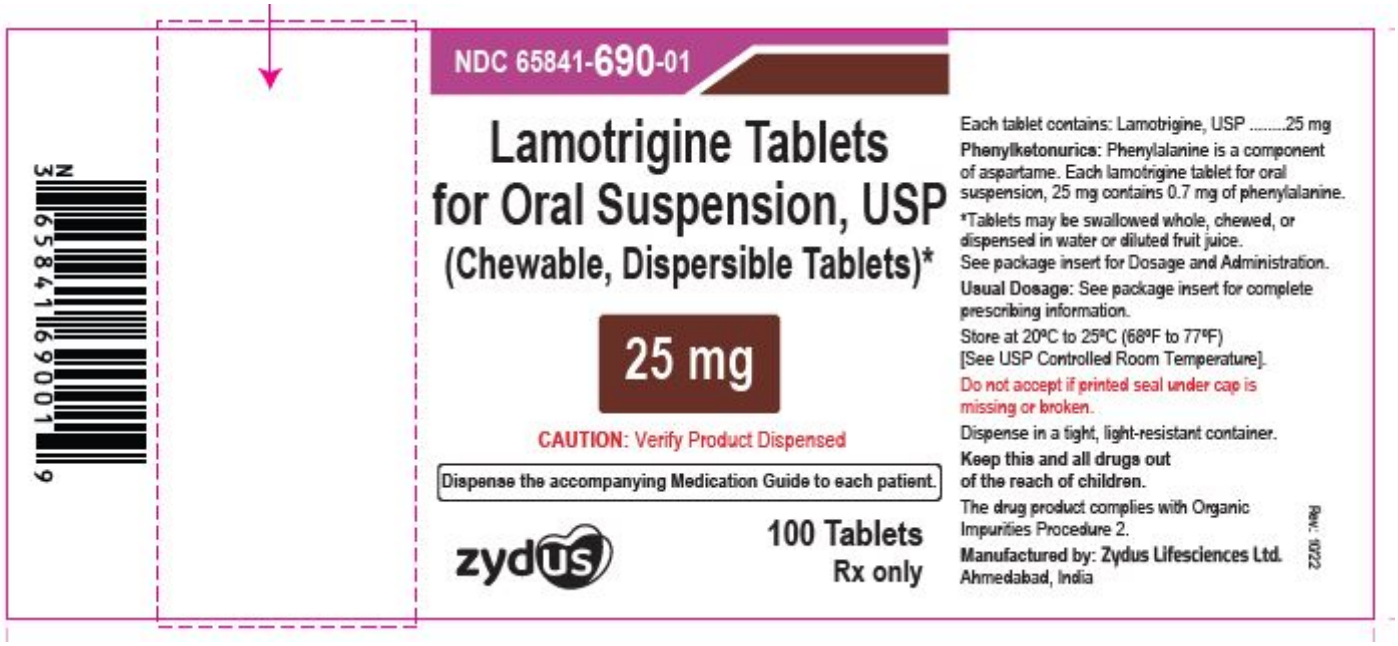
Lamotrigine Tablets (Chewable, Dispersible), 5 mg

Lamotrigine Tablets (Chewable, Dispersible), 25 mg

NDC 65841-690-01 in bottle of 100 tablets

100 tablets

Rx only



Lamotrigine Tablets (Chewable, Dispersible), 25 mg

Lamotrigine Tablets USP, 25 mg

NDC 65841-682-01 in bottle of 100 tablets

100 tablets

Rx only

Lamotrigine Tablets USP, 25 mg

Lamotrigine Tablets USP, 50 mg

NDC 65841-683-01 in bottle of 100 tablets

100 tablets

Rx only

Lamotrigine Tablets USP, 50 mg

Lamotrigine Tablets USP, 100 mg

NDC 65841-684-01 in bottle of 100 tablets

100 tablets

Rx only

Lamotrigine Tablets USP, 100 mg

Lamotrigine Tablets USP, 150 mg

NDC 65841-685-14 in bottle of 60 tablets

60 tablets

Rx only

Lamotrigine Tablets USP, 150 mg

Lamotrigine Tablets USP, 200 mg

NDC 65841-686-14 in bottle of 60 tablets

60 tablets

Rx only

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

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: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	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: OP1R32D61U)	

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: U3H27498KS) (LAMOTRIGINE - UNII:U3H27498KS)	LAMOTRIGINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
CROSCARMELLOSE 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)	
CROSCARMELLOSE 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 - 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: 9/2023 Zydus Lifesciences Limited