LAMICTAL

lamotrigine tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0173-0644
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 2	
LACTOSE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONES	
SODIUM STARCH GLYCOLATE TYPE A POTATO	

Product Characteristics

Color	BLUE	**Score**	2 pieces
Shape	HEXAGON (6 sided)	**Size**	12mm
Flavor		**Imprint Code**	LAMICTAL;200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0644-60	60 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020241	01/18/1995	

LAMICTAL

lamotrigine tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0173-

Product Type	LABEL	**Item Code (Source)**	0699
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	2 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED	
MAGNESIUM STEARATE	
POVIDONES	
SACCHARIN SODIUM	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
MAGNESIUM ALUMINUM SILICATE	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND	**Size**	5mm
Flavor	BLACKBERRY (blackcurrant)	**Imprint Code**	LTG;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0699-02	30 in 1 BOTTLE		
2	NDC:0173-0699-00	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020764	10/12/2000	

LAMICTAL

lamotrigine tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0173-0526
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED	
MAGNESIUM STEARATE	
POVIDONES	
SACCHARIN SODIUM	
MAGNESIUM ALUMINUM SILICATE	
SODIUM STARCH GLYCOLATE TYPE A POTATO	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	no score
Shape	OVAL (caplet-shaped)	**Size**	8mm
Flavor	BLACKBERRY (blackcurrant)	**Imprint Code**	GX;CL2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0526-00	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020764	09/04/1998	

LAMICTAL

lamotrigine tablet, chewable

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0173-0527
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM CARBONATE	
HYDROXYPROPYL CELLULOSE, LOW SUBSTITUTED	
MAGNESIUM STEARATE	
POVIDONES	
SACCHARIN SODIUM	
SODIUM STARCH GLYCOLATE TYPE A POTATO	
MAGNESIUM ALUMINUM SILICATE	

Product Characteristics

Color	WHITE	**Score**	no score
Shape	OVAL (super elliptical-shaped)	**Size**	5mm
Flavor	BLACKBERRY (blackcurrant)	**Imprint Code**	GX;CL5
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0527-00	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020764	09/03/1998	

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0173-0772
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	

SUCRALOSE

ETHYLCELLULOSE (100 MPA.S)

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	7mm
Flavor	CHERRY	**Imprint Code**	LMT;25
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0772-02	30 in 1 DOSE PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0173-0774
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	9mm
Flavor	CHERRY	**Imprint Code**	LMT;50

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0774-02	30 in 1 DOSE PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0173-0776
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	100 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	11mm
Flavor	CHERRY	**Imprint Code**	LAMICTAL;100
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0776-02	30 in 1 DOSE PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	**Item Code (Source)**	NDC:0173-0777
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	200 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	14mm
Flavor	CHERRY	**Imprint Code**	LAMICTAL;200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0777-02	30 in 1 DOSE PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

LAMICTAL

lamotrigine kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0173-0594

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0594-02	1 in 1 PACKAGE, COMBINATION		
1		1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	7	
Part 2	42	

Part 1 of 2

LAMICTAL

lamotrigine tablet

Product Information

Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	100 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONES	
FD&C YELLOW NO. 6	
SODIUM STARCH GLYCOLATE TYPE A POTATO	

Product Characteristics

Color	ORANGE (peach)	Score	2 pieces
Shape	HEXAGON (6 sided)	Size	11mm

Flavor		**Imprint Code**	LAMICTAL;100
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020241	01/17/1995	

Part 2 of 2

LAMICTAL

lamotrigine tablet

Product Information

Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONES	
SODIUM STARCH GLYCOLATE TYPE A POTATO	

Product Characteristics

Color	WHITE	**Score**	2 pieces
Shape	HEXAGON (6 sided)	**Size**	6mm
Flavor		**Imprint Code**	LAMICTAL;25
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020241	08/15/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020241	09/29/2003	

LAMICTAL ODT

lamotrigine kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0173-0779

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0779-00	1 in 1 PACKAGE, COMBINATION		
1		1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		7
Part 2		21

Part 1 of 2

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information

Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	9mm
Flavor	CHERRY	**Imprint Code**	LMT;50
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

Part 2 of 2

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information			
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	7mm
Flavor	CHERRY	**Imprint Code**	LMT;25
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

LAMICTAL ODT

lamotrigine kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0173-0780

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0780-00	1 in 1 PACKAGE, COMBINATION		
1		1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	42	
Part 2	14	

Part 1 of 2

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information

Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	9mm
Flavor	CHERRY	**Imprint Code**	LMT;50
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

Part 2 of 2

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information			
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	100 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	11mm
Flavor	CHERRY	**Imprint Code**	LAMICTAL;100
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

NDA	NDA022251	06/05/2009

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

LAMICTAL ODT

lamotrigine kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0173-0778

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0778-00	1 in 1 PACKAGE, COMBINATION		
1		1 in 1 BLISTER PACK		
2	NDC:0173-0778-61	1 in 1 PACKAGE, COMBINATION		
2		1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1		14
Part 2		14
Part 3		7

Part 1 of 3

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information

Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	7mm
Flavor	CHERRY	**Imprint Code**	LMT;25
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

Part 2 of 3

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information

Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	50 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	9mm
Flavor	CHERRY	**Imprint Code**	LMT;50
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

Part 3 of 3

LAMICTAL ODT

lamotrigine tablet, orally disintegrating

Product Information

Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	100 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE	
MANNITOL	
SUCRALOSE	
ETHYLCELLULOSE (100 MPA.S)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	no score
Shape	ROUND (flat-faced, radius edge)	**Size**	11mm
Flavor	CHERRY	**Imprint Code**	LAMICTAL;100
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022251	06/05/2009	

LAMICTAL
lamotrigine kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0173-0817

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0173-0817-28	1 in 1 PACKAGE, COMBINATION		
1		1 in 1 BLISTER PACK		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	14	
Part 2	84	

Part 1 of 2

LAMICTAL
lamotrigine tablet

Product Information

Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	100 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONES	
FD&C YELLOW NO. 6	
SODIUM STARCH GLYCOLATE TYPE A POTATO	

Product Characteristics

Color	ORANGE (peach)	**Score**	2 pieces
Shape	HEXAGON (6 sided)	**Size**	11mm
Flavor		**Imprint Code**	LAMICTAL;100
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020241	01/17/1995	

Part 2 of 2

LAMICTAL

lamotrigine tablet

Product Information

Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LAMOTRIGINE (LAMOTRIGINE)	LAMOTRIGINE	25 mg

Inactive Ingredients

Ingredient Name	Strength
LACTOSE	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POVIDONES	
SODIUM STARCH GLYCOLATE TYPE A POTATO	

Product Characteristics

Color	WHITE	**Score**	2 pieces
Shape	HEXAGON (6 sided)	**Size**	6mm
Flavor		**Imprint Code**	LAMICTAL;25
Contains			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020241	08/15/1996	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020241	09/29/2003	

Labeler - GlaxoSmithKline LLC (167380711)

Revised: 9/2012 GlaxoSmithKline LLC

LITHIUM CARBONATE- lithium carbonate tablet, film coated, extended release
Mylan Institutional Inc.

WARNING: Lithium toxicity is closely related to serum lithium levels and can occur at doses close to therapeutic levels. Facilities for prompt and accurate serum lithium determinations should be available before initiating therapy (see DOSAGE AND ADMINISTRATION).

DESCRIPTION

Lithium carbonate extended-release tablets, USP contain lithium carbonate, USP, a white, granular, odorless powder with molecular formula Li_2CO_3 and molecular weight 73.89. It is sparingly soluble in water, very slightly soluble in alcohol and dissolves, with effervescence in dilute mineral acids. Lithium is an element of the alkali-metal group with atomic number 3, atomic weight 6.94 and an emission line at 671 nm on the flame photometer. Each peach film-coated, extended-release tablet contains 300 mg of lithium carbonate, USP. This slowly dissolving film-coated tablet is designed to give lower serum lithium peak concentrations than obtained with conventional oral lithium dosage forms. Inactive ingredients consist of calcium stearate, hypromellose, polydextrose, povidone, polyethylene glycol, red iron oxide, sodium chloride, sodium lauryl sulfate, sorbitol, titanium dioxide, triacetin and yellow iron oxide. Product meets USP Drug Release Test 1.

ACTIONS

Preclinical studies have shown that lithium alters sodium transport in nerve and muscle cells and effects a shift toward intraneuronal metabolism of catecholamines, but the specific biochemical mechanism of lithium action in mania is unknown.

INDICATIONS

Lithium carbonate extended-release tablets are indicated in the treatment of manic episodes of Bipolar Disorder. Bipolar Disorder, Manic (DSM-IV) is equivalent to Manic Depressive illness, Manic, in the older DSM-II terminology. Lithium carbonate extended-release tablets are also indicated as a maintenance treatment for individuals with a diagnosis of Bipolar Disorder. Maintenance therapy reduces the frequency of manic episodes and diminishes the intensity of those episodes which may occur.

Typical symptoms of mania include pressure of speech, motor hyperactivity, reduced need for sleep, flight of ideas, grandiosity, elation, poor judgment, aggressiveness and possibly hostility. When given to a patient experiencing a manic episode, lithium may produce a normalization of symptomatology within 1 to 3 weeks.

WARNINGS

Lithium Toxicity

Lithium toxicity is closely related to serum lithium concentrations and can occur at doses close to therapeutic concentrations (see DOSAGE AND ADMINISTRATION).

Outpatients and their families should be warned that the patient must discontinue lithium therapy and contact his physician if such clinical signs of lithium toxicity as diarrhea, vomiting, tremor, mild ataxia, drowsiness or muscular weakness occur.

Lithium should generally not be given to patients with significant renal or cardiovascular disease, severe debilitation, dehydration, sodium depletion, and to patients receiving diuretics, or angiotensin converting enzyme (ACE) inhibitors, since the risk of lithium toxicity is very high in such patients. If the psychiatric indication is life threatening and if such a patient fails to respond to other measures, lithium treatment may be undertaken with extreme caution, including daily serum lithium determinations and adjustment to the usually low doses ordinarily tolerated by these individuals. In such instances, hospitalization is a necessity.

Unmasking of Brugada Syndrome

There have been post-marketing reports of a possible association between treatment with lithium and the unmasking of Brugada Syndrome. Brugada Syndrome is a disorder characterized by abnormal