Med Choice CNS

Lamotrigine

Lamicdin

50 mg Tablet

ANTICONVULSANT

℞

FORMULATION:
Each tablet contains:
Lamotrigine..... 50 mg

PRODUCT DESCRIPTION:
A white, round, biconvex, uncoated tablets.

PHARMACODYNAMICS:
Mechanism of action
The results of pharmacological studies suggest that lamotrigine is a use- and voltage-dependent blocker of voltage-gated sodium channels. It inhibits sustained repetitive firing of neurons and inhibits release of glutamate (the neurotransmitter which plays a key role in the generation of epileptic seizures). These effects are likely to contribute to the anticonvulsant properties of lamotrigine.
In contrast, the mechanisms by which lamotrigine exerts its therapeutic action in bipolar disorder have not been established, although interaction with voltage-gated sodium channels is likely to be important.

Pharmacodynamic effects
In tests designed to evaluate the central nervous system effects of medicinal products, the results obtained using doses of 240 mg lamotrigine administered to healthy volunteers did not differ from placebo, whereas both 1000 mg phenytoin and 10 mg diazepam each significantly impaired fine visual motor coordination and eye movements, increased body sway and produced subjective sedative effects.
In another study, single oral doses of 600 mg carbamazepine significantly impaired fine visual motor coordination and eye movements, while increasing both body sway and heart rate, whereas results with lamotrigine at doses of 150 mg and 300 mg did not differ from placebo.

PHARMACOKINETICS:
Lamotrigine is well-absorbed from gastrointestinal tract and peak plasma concentrations occur approximately 2.5 hours after oral dose. It is widely distributed in the body and is reported to be about 55% bound to plasma proteins. It is extensively metabolized in the liver and excreted almost entirely in urine, principally as a glucuronide conjugate. It slightly induces its own metabolism and the half-life at steady state is reported to be about 24 hours. Lamotrigine is distributed in breast milk.

INDICATIONS:
For monotherapy and adjunctive treatment of partial seizures and primary and secondary generalized tonic-clonic seizures; seizures associated with Lennox-Gastaut Syndrome.

DOSAGE AND ADMINISTRATION:
Initial adult dose: Monotherapy: 25 mg once daily for 2 weeks followed by 50 mg once daily for 2 weeks, thereafter the dose is increased by maximum 50 mg to 100 mg every 1 to 2 weeks.
Maintenance dose: 100 mg to 200 mg daily.
Bipolar disorder: 100 mg to 200 mg daily.
Or as prescribed by the physician.

CONTRAINDICATION:
Hypersensitivity to active ingredient or any component of the formulation.

PRECAUTION:
Lamotrigine should be given with caution to patients with hepatic or renal impairment. Patients receiving lamotrigine should be closely monitored especially for changes in hepatic, renal, and clotting functions.

PREGNANCY:
The use of lamotrigine is not recommended for use in pregnancy.

LACTATION:
Lamotrigine is distributed in breast milk and therefore should be avoided during breastfeeding.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Skin rash
There have been reports of adverse skin reactions, which have generally occurred within the first eight weeks after initiation of lamotrigine treatment. The majority of rashes are mild and self-limiting, however serious rashes requiring hospitalization and discontinuation of lamotrigine have also been reported. These have included potentially life-threatening rashes such as Stevens-Johnson Syndrome and toxic epidermal necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

In adults enrolled in studies utilizing the current lamotrigine dosing recommendations, the incidence of serious skin rashes is approximately 1 in 500 in epilepsy patients. Approximately half of these cases have been reported as Stevens–Johnson Syndrome (1 in 1000). In clinical trials in patients with bipolar disorder, the incidence of serious rash is approximately 1 in 1000.

The risk of serious skin rashes in children is higher than in adults. Available data from a number of studies suggest the incidence of rashes associated with hospitalization in epileptic children is from 1 in 300 to 1 in 100.

In children, the initial presentation of a rash can be mistaken for an infection, physicians should consider the possibility of a reaction to lamotrigine treatment in children that develop symptoms of rash and fever during the first eight weeks of therapy.

Additionally, the overall risk of rash appears to be strongly associated with:
• High initial doses of lamotrigine and exceeding the recommended dose escalation of lamotrigine therapy.
• Concomitant use of valproate.

Caution is also required when treating patients with a history of allergy or rash to other anti-epileptic drugs (AEDs) as the frequency of non-serious rash after treatment with lamotrigine was approximately three times higher in these patients than in those without such history.
All patients (adults and children) who develop a rash should be promptly evaluated and lamotrigine withdrawn immediately unless the rash is clearly not related to lamotrigine treatment. It is recommended that lamotrigine should not be restarted in patients who have discontinued due to rash associated with prior treatment with lamotrigine unless the potential benefit clearly outweighs the risk. If the patient has developed SJS or TEN with the use of lamotrigine, treatment with lamotrigine must not be restarted in this patient at any time.
Rash has also been reported as part of a hypersensitivity syndrome associated with a variable pattern of systemic symptoms including fever, lymphadenopathy, facial edema, abnormalities of the blood and liver and aseptic meningitis. The syndrome shows a wide spectrum of clinical severity and may rarely lead to disseminated intravascular coagulation (DIC) and multiorgan failure. It is important to note that early manifestations of hypersensitivity (e.g., fever, lymphadenopathy) may be present even though rash is not evident. If such signs and symptoms are present, the patient should be evaluated immediately and lamotrigine tablets discontinued if an alternative aetiology cannot be established.

Aseptic meningitis was reversible on withdrawal of the drug in most cases, but recurred in a number of cases on re-exposure to lamotrigine. Re-exposure resulted in a rapid return of symptoms that were frequently more severe. Lamotrigine should not be restarted in patients who have discontinued due to aseptic meningitis associated with prior treatment of lamotrigine.

Clinical worsening and suicide risk
Suicidal ideation and behavior have been reported in patients treated with AEDs in several indications. A meta-analysis of randomized placebo-controlled trials of AEDs has also shown a small increased risk of suicidal ideation and behavior. The mechanism of this risk is not known and the available data do not exclude the possibility of an increased risk for lamotrigine.
Therefore, patients should be monitored for signs of suicidal ideation and behaviors and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behavior emerge.
In patients with bipolar disorder, worsening of depressive symptoms and/or the emergence of suicidality may occur whether or not they are taking medications for bipolar disorder, including lamotrigine. Therefore, patients receiving lamotrigine for bipolar disorder should be closely monitored for clinical worsening (including development of new symptoms) and suicidality, especially at the beginning of a course of treatment, or at the time of dose changes. Certain patients, such as those with a history of suicidal behavior or thoughts, young adults, and those patients exhibiting a significant degree of suicidal ideation prior to commencement of treatment, may be at a greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment.
Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients who experience clinical worsening (including development of new symptoms) and/or the emergence of suicidal ideation/behavior, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Hormonal contraceptives
Effects of hormonal contraceptives on lamotrigine efficacy
The use of an ethinyloestradiol/levonorgestrel (30 µg/150 µg) combination increases the clearance of lamotrigine by approximately two-fold resulting in decreased lamotrigine levels. A decrease in lamotrigine levels has been associated with loss of seizure control. Following titration, higher maintenance doses of lamotrigine (by as much as two-fold) will be needed in most cases to attain a maximal therapeutic response. When stopping hormonal contraceptives, the clearance of lamotrigine may be halved. Increases in lamotrigine concentrations may be associated with dose-related adverse events. Patients should be monitored with respect to this.
In women not already taking an inducer of lamotrigine glucuronidation and taking a hormonal contraceptive that includes one week of inactive treatment (for example, "pill-free week") gradual transient increases in lamotrigine levels will occur during the week of inactive treatment. Variations in lamotrigine levels of this order may be associated with adverse effects. Therefore, consideration should be given to using contraception without a pill-free week, as first-line therapy (for example, continuous hormonal contraceptives or non-hormonal methods).
The interaction between other oral contraceptives or hormone therapy (HRT) treatments and lamotrigine have not been studied, though they may similarly affect lamotrigine pharmacokinetic parameters.

Effects of lamotrigine on hormonal contraceptive efficacy
An interaction study in 16 healthy volunteers has shown that when lamotrigine and a hormonal contraceptive (ethinyloestradiol/levonorgestrel combination) are administered in combination, there is a modest increase in levonorgestrel clearance and changes in serum FSH and LH. The impact of these changes on ovarian ovulatory activity is unknown. However, the possibility of these changes resulting in decreased contraceptive efficacy in some patients taking hormonal preparations with lamotrigine cannot be excluded. Therefore, patients should be instructed to promptly report changes in their menstrual pattern, (i.e., breakthrough bleeding).

Dihydrofolate reductase
Lamotrigine has a slight inhibitory effect on dihydrofolic acid reductase; hence, there is a possibility of interference with folate metabolism during long-term therapy. However, during prolonged human dosing, lamotrigine did not induce significant changes in the hemoglobin concentration, mean corpuscular volume, or serum or red blood cell folate concentrations up to 1 year or red blood cell folate concentrations for up to 5 years.

Renal failure
In single dose studies in subjects with end stage renal failure, plasma concentrations of lamotrigine were not significantly altered. However, accumulation of the glucuronide metabolite is to be expected; caution should therefore be exercised in treating patients with renal failure.

Patients taking other preparations containing lamotrigine
Lamotrigine should not be administered to patients currently being treated with any other preparation containing lamotrigine without consulting a doctor.

Excipient of Lamotrigine tablets
Lamotrigine tablets contain lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Development in children
There are no data on the effect of lamotrigine on growth, sexual maturation and cognitive, emotional and behavioral developments in children.

Precautions relating to epilepsy
As with other AEDs, abrupt withdrawal of lamotrigine tablets may provoke rebound seizures. Unless safety concerns (for example, rash) require an abrupt withdrawal, the dose of lamotrigine tablets should be gradually decreased over a period of two weeks.
There are reports in the literature that severe convulsive seizures including status epilepticus may lead to rhabdomyolysis, multiorgan dysfunction and disseminated intravascular coagulation, sometimes with fatal outcome. Similar cases have occurred in association with the use of lamotrigine.
A clinically significant worsening of seizure frequency instead of an improvement may be observed. In patients with more than one seizure type, the observed benefit of control for one seizure type should be weighed against any observed worsening in another seizure type.

Myoclonic seizures may be worsened by lamotrigine
There is a suggestion in the data that responses in combination with enzyme inducers is less than in combination with non-enzyme inducing anticonvulsant agents. The reason is unclear.
In children taking lamotrigine for the treatment of typical absence seizures, efficacy may not be maintained in all patients.

Precautions relating to bipolar disorder
Children and adolescents below 18 years
Treatment with antidepressants is associated with an increased risk of suicidal thinking and behavior in children and adolescents with major depressive disorder and other psychiatric disorders.

Brugada-type ECG
Arrhythmogenic ST-T abnormality and typical Brugada ECG pattern has been reported in patients treated with lamotrigine. The use of lamotrigine should be carefully considered in patients with Brugada syndrome.

Hemophagocytic lymphohistiocytosis (HLH)
HLH has been reported in patients taking lamotrigine. HLH is characterised by signs and symptoms, like fever, rash, neurological symptoms, hepatosplenomegaly, lymphadenopathy, cytopenias, high serum ferritin, hypertriglyceridemia and abnormalities of liver function and coagulation. Symptoms occur generally within 4 weeks of treatment initiation. HLH can be life-threatening.
Patients should be informed of the symptoms associated with HLH and should be advised to seek medical attention immediately if they experience these symptoms while on lamotrigine therapy.
Immediately evaluate patients who develop these signs and symptoms and consider a diagnosis of HLH. Lamotrigine should be promptly discontinued unless an alternative aetiology can be established.

ADVERSE DRUG REACTIONS:
Skin rashes may occur during therapy with lamotrigine; severe skin reaction including Stevens-Johnson Syndrome have been reported in children and usually occur within 8 weeks of starting lamotrigine.

Symptoms such as fever, malaise, flu-like symptoms, drowsiness, lymphadenopathy, facial edema, rarely hepatic dysfunction, leukopenia and thrombocytopenia have also been reported with rashes as part of hypersensitivity syndrome.

Other adverse effects include angioedema and photosensitivity, diplopia, blurred vision, conjunctivitis and dizziness, drowsiness, insomnia, headache, ataxia, nystagmus, tremor, tiredness, nausea and vomiting, irritability and aggression, hallucinations, agitation and confusion. Very rarely lupus-like reactions have been reported.

DRUG INTERACTIONS:
There are complex interactions between anticonvulsant drugs and toxicity may be enhanced by the enzyme inducers carbamazepine, phenytoin, phenobarbital, and primidone, and inhibited by valproate.

OVERDOSE AND TREATMENT:
Acute ingestion of doses in excess of 10 to 20 times the maximum therapeutic dose has been reported. Overdose has resulted in symptoms including nystagmus, ataxia, impaired consciousness and coma.
In the event of overdosage, the patient should be admitted to hospital and given appropriate supportive therapy. Therapy aimed at decreasing absorption (activated charcoal, laxative or gastric lavage) should be performed if indicated. Further management should be as clinically indicated. There is no experience with hemodialysis as treatment of overdose. In six volunteers with kidney failure, 20% of the lamotrigine was removed from the body during a 4-hour hemodialysis session.

CAUTION:
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction."

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

AVAILABILITY:
Alu/Alu Blister Pack x 10's (Box of 30's)

DRP-3340-
Date of First Authorization:
Date of Revision of Package Insert: May 19, 2021

PL 00480-04

Manufactured by:
XL LABORATORIES PVT. LTD.
E-1223, Phase I Ext. (Ghatal) RIICO Industrial Area, Bhiwadi, Dist. Alwar, Rajasthan, India

Imported by:
AMBICA INTERNATIONAL CORPORATION
No. 9 Amsterdam Extension, Merville Park Subd., Parañaque, Metro Manila

Distributed by:
MEDCHOICE CNS PHARMA CORPORATION
10F Unit 1001 88 Corporate Center, Sedeño cor. Valero Sts., Salcedo Village, Makati City, Metro Manila

Size : 165x120 mm

MedChoice CNS

Lamotrigine

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100 mg Tablet

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Pharmacode

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PHARMACOKINETICS:
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PREGNANCY:
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LACTATION:
Lamotrigine is distributed in breast milk and therefore, should be avoided during breastfeeding.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Skin rash
There have been reports of adverse skin reactions, which have generally occurred within the first eight weeks after initiation of lamotrigine treatment. The majority of rashes are mild and self-limiting, however, serious rashes requiring hospitalization and discontinuation of lamotrigine have also been reported. These have included potentially life-threatening rashes such as Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

In adults enrolled in studies utilizing the current lamotrigine dosing recommendations, the incidence of serious skin rashes is approximately 1 in 500 in epilepsy patients. Approximately half of these cases have been reported as Stevens–Johnson Syndrome (1 in 1000). In clinical trials in patients with bipolar disorder, the incidence of serious rash is approximately 1 in 1000.

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In children, the initial presentation of a rash can be mistaken for an infection, physicians should consider the possibility of a reaction to lamotrigine treatment in children that develop symptoms of rash and fever during the first eight weeks of therapy.

Additionally, the overall risk of rash appears to be strongly associated with:
• High initial doses of lamotrigine and exceeding the recommended dose escalation of lamotrigine therapy.
• Concomitant use of valproate.

Caution is also required when treating patients with a history of allergy or rash to other anti-epileptic drugs (AEDs) as the frequency of non-serious rash after treatment with lamotrigine was approximately three times higher in these patients than in those without such history.
All patients (adults and children) who develop a rash should be promptly evaluated and lamotrigine withdrawn immediately unless the rash is clearly not related to lamotrigine treatment. It is recommended that lamotrigine should not be restarted in patients who have discontinued due to rash associated with prior treatment with lamotrigine unless the potential benefit clearly outweighs the risk. If the patient has developed SJS or TEN with the use of lamotrigine, treatment with lamotrigine must not be restarted in this patient at any time.
Rash has also been reported as part of a hypersensitivity syndrome associated with a variable pattern of systemic symptoms including fever, lymphadenopathy, facial edema, abnormalities of the blood and liver and aseptic meningitis. The syndrome shows a wide spectrum of clinical severity and may rarely lead to disseminated intravascular coagulation (DIC) and multiorgan failure. It is important to note that early manifestations of hypersensitivity (e.g., fever, lymphadenopathy) may be present even though rash is not evident. If such signs and symptoms are present, the patient should be evaluated immediately and lamotrigine tablets discontinued if an alternative etiology cannot be established.

Aseptic meningitis was reversible on withdrawal of the drug in most cases, but recurred in a number of cases on re-exposure to lamotrigine. Re-exposure resulted in a rapid return of symptoms that were frequently more severe. Lamotrigine should not be restarted in patients who have discontinued due to aseptic meningitis associated with prior treatment of lamotrigine.

Clinical worsening and suicide risk
Suicidal ideation and behavior have been reported in patients treated with AEDs in several indications. A meta-analysis of randomized placebo-controlled trials of AEDs has also shown a small increased risk of suicidal ideation and behavior. The mechanism of this risk is not known and the available data do not exclude the possibility of an increased risk for lamotrigine.
Therefore, patients should be monitored for signs of suicidal ideation and behaviors and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behavior emerge.
In patients with bipolar disorder, worsening of depressive symptoms and/or the emergence of suicidality may occur whether or not they are taking medications for bipolar disorder, including lamotrigine. Therefore, patients receiving lamotrigine for bipolar disorder should be closely monitored for clinical worsening (including development of new symptoms) and suicidality, especially at the beginning of a course of treatment, or at the time of dose changes. Certain patients, such as those with a history of suicidal behavior or thoughts, young adults, and those patients exhibiting a significant degree of suicidal ideation prior to commencement of treatment, may be at a greater risk of suicidal thoughts or suicide attempts, and should receive careful monitoring during treatment.
Consideration should be given to changing the therapeutic regimen, including possibly discontinuing the medication, in patients who experience clinical worsening (including development of new symptoms) and/or the emergence of suicidal ideation/behavior, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms.

Hormonal contraceptives
Effects of hormonal contraceptives on lamotrigine efficacy
The use of an ethinyloestradiol/levonorgestrel (30 µg/150 µg) combination increases the clearance of lamotrigine by approximately two-fold resulting in decreased lamotrigine levels. A decrease in lamotrigine levels has been associated with loss of seizure control. Following titration, higher maintenance doses of lamotrigine (by as much as two-fold) will be needed in most cases to attain a maximal therapeutic response. When stopping hormonal contraceptives, the clearance of lamotrigine may be halved. Increases in lamotrigine concentrations may be associated with dose-related adverse events. Patients should be monitored with respect to this.
In women not already taking an inducer of lamotrigine glucuronidation and taking a hormonal contraceptive that includes one week of inactive treatment (for example, "pill-free week") gradual transient increases in lamotrigine levels will occur during the week of inactive treatment. Variations in lamotrigine levels of this order may be associated with adverse effects. Therefore, consideration should be given to using contraception without a pill-free week, as first-line therapy (for example, continuous hormonal contraceptives or non-hormonal methods).
The interaction between other oral contraceptives or hormone therapy (HRT) treatments and lamotrigine have not been studied, though they may similarly affect lamotrigine pharmacokinetic parameters.

Effects of lamotrigine on hormonal contraceptive efficacy
An interaction study in 16 healthy volunteers has shown that when lamotrigine and a hormonal contraceptive (ethinyloestradiol/levonorgestrel combination) are administered in combination, there is a modest increase in levonorgestrel clearance and changes in serum follicle stimulating hormone (FSH) and luteinizing hormone (LH). The impact of these changes on ovarian ovulatory activity is unknown. However, the possibility of these changes resulting in decreased contraceptive efficacy in some patients taking hormonal preparations with lamotrigine cannot be excluded. Therefore, patients should be instructed to promptly report changes in their menstrual pattern, (i.e., breakthrough bleeding).

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Lamotrigine has a slight inhibitory effect on dihydrofolic acid reductase; hence, there is a possibility of interference with folate metabolism during long-term therapy. However, during prolonged human dosing, lamotrigine did not induce significant changes in the hemoglobin concentration, mean corpuscular volume, or serum or red blood cell folate concentrations up to 1 year or red blood cell folate concentrations for up to 5 years.

Renal failure
In single dose studies in subjects with end stage renal failure, plasma concentrations of lamotrigine were not significantly altered. However, accumulation of the glucuronide metabolite is to be expected; caution should therefore be exercised in treating patients with renal failure.

Patients taking other preparations containing lamotrigine
Lamotrigine should not be administered to patients currently being treated with any other preparation containing lamotrigine without consulting a doctor.

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Lamotrigine tablets contain lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Development in children
There are no data on the effect of lamotrigine on growth, sexual maturation and cognitive, emotional and behavioral developments in children.

Precautions relating to epilepsy
As with other AEDs, abrupt withdrawal of lamotrigine tablets may provoke rebound seizures. Unless safety concerns (for example, rash) require an abrupt withdrawal, the dose of lamotrigine tablets should be gradually decreased over a period of two weeks.
There are reports in the literature that severe convulsive seizures including status epilepticus may lead to rhabdomyolysis, multiorgan dysfunction and disseminated intravascular coagulation, sometimes with fatal outcome. Similar cases have occurred in association with the use of lamotrigine.
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Patients should be informed of the symptoms associated with HLH and should be advised to seek medical attention immediately if they experience these symptoms while on lamotrigine therapy.
Immediately evaluate patients who develop these signs and symptoms and consider a diagnosis of HLH. Lamotrigine should be promptly discontinued unless an alternative etiology can be established.

ADVERSE DRUG REACTIONS:
Skin rashes may occur during therapy with lamotrigine; severe skin reaction including Stevens-Johnson Syndrome have been reported in children and usually occur within 8 weeks of starting lamotrigine.

Symptoms such as fever, malaise, flu-like symptoms, drowsiness, lymphadenopathy, facial edema, rarely hepatic dysfunction, leukopenia and thrombocytopenia have also been reported with rashes as part of hypersensitivity syndrome.

Other adverse effects include angioedema and photosensitivity, diplopia, blurred vision, conjunctivitis and dizziness, drowsiness, insomnia, headache, ataxia, nystagmus, tremor, tiredness, nausea and vomiting, irritability and aggression, hallucinations, agitation and confusion. Very rarely lupus-like reactions have been reported.

Pharmacode

DRUG INTERACTIONS:
There are complex interactions between anticonvulsant drugs and toxicity may be enhanced by the enzyme inducers carbamazepine, phenytoin, phenobarbital, and primidone, and inhibited by valproate.

OVERDOSE AND TREATMENT:
Acute ingestion of doses in excess of 10 to 20 times the maximum therapeutic dose has been reported. Overdose has resulted in symptoms including nystagmus, ataxia, impaired consciousness and coma.
In the event of overdosage, the patient should be admitted to hospital and given appropriate supportive therapy. Therapy aimed at decreasing absorption (activated charcoal, laxative or gastric lavage) should be performed if indicated. Further management should be as clinically indicated. There is no experience with hemodialysis as treatment of overdose. In six volunteers with kidney failure, 20% of the lamotrigine was removed from the body during a 4-hour hemodialysis session.

CAUTION:
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Seek medical attention immediately at the first sign of any adverse drug reaction."

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

AVAILABILITY:
Alu/Alu Blister Pack x 10's (Box of 30's)

DRP-3283-02
Date of First Authorization: September 3, 2021
Date of Revision of Package Insert: January 14, 2022

Manufactured by:
XL LABORATORIES PVT. LTD.
E-1223, Phase I, Ext. (Ghatal) RIICO Industrial Area,
Bhiwadi, Dist. Alwar, Rajasthan, India
Imported by:
AMBICA INTERNATIONAL CORPORATION
No. 9 Amsterdam Extension, Merville Park Subd.,
Parañaque City, Metro Manila
Distributed by:
MEDCHOICE CNS PHARMA CORPORATION
10F Unit 1001 88 Corporate Center, Sedeño cor.
Valero Sts., Salcedo Village, Makati, Metro Manila

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