Lamictal (lamotrigine) is a drug of the phenyltriazine class chemically unrelated to existing antiepileptic drugs (AEDs). Lamotrigine is thought to act at voltage-sensitive sodium channels to stabilize neuronal membranes and inhibit the flow of sodium into neurons. The plasma concentration (Cmax) following oral administration of lamotrigine concentrations of 12 healthy elderly volunteers was 0.5 to 2.2 ng/mL. The plasma concentration of lamotrigine in patients with liver impairment has not been evaluated. The pharmacokinetics of lamotrigine in patients with impaired liver function have not been evaluated.

Contraindications: Lamictal (lamotrigine) is contraindicated in patients with known hypersensitivity to lamotrigine or to any components of LAMICTAL. It is not recommended for use in patients with hepatic impairment or cirrhosis.

Warnings: Lamictal (lamotrigine) should be used with caution in patients with the following conditions: severe hepatic impairment, severe renal impairment, severe respiratory disease, and patients who are receiving concomitant valproic acid (VPA), particularly in the absence of enzyme-inducing AEDs.

Adverse Drug Reactions: Lamictal (lamotrigine) can cause serious adverse reactions, including rash, dizziness, ataxia, nausea, diplopia, and blurred vision. Lamictal (lamotrigine) should be used with caution in patients with a history of serious rash in patients receiving other AEDs. Lamictal (lamotrigine) should be used with caution in patients with a history of serious rash in patients receiving other AEDs.

Drug Interactions: Lamictal (lamotrigine) can interact with other AEDs, including carbamazepine, phenobarbital, phenytoin, and primidone. Such interactions can increase the plasma concentration of lamotrigine and can reduce the plasma concentration of concomitantly administered AEDs.

Pharmacology: Lamictal (lamotrigine) is a drug of the phenyltriazine class chemically unrelated to existing antiepileptic drugs (AEDs).

Pharmacokinetics: Lamictal (lamotrigine) is rapidly absorbed following oral administration. The absolute bioavailability of lamotrigine following oral administration is approximately 70% of the oral dose. The peak plasma concentration of lamotrigine occurs approximately 1 to 2 hours after oral administration. The plasma concentration of lamotrigine is increased in patients with renal impairment. The plasma concentration of lamotrigine is decreased in patients with hepatic impairment. The plasma concentration of lamotrigine is increased in patients with a history of serious rash in patients receiving other AEDs.

Pharmacodynamics: Lamictal (lamotrigine) is a drug of the phenyltriazine class chemically unrelated to existing antiepileptic drugs (AEDs). Lamictal (lamotrigine) is a drug of the phenyltriazine class chemically unrelated to existing antiepileptic drugs (AEDs). Lamictal (lamotrigine) is a drug of the phenyltriazine class chemically unrelated to existing antiepileptic drugs (AEDs).

Clinical Trials: Lamictal (lamotrigine) has been shown to be effective in reducing seizure frequency in patients with epilepsy. Lamictal (lamotrigine) is approved by the US Food and Drug Administration (FDA) for the treatment of partial seizures in patients with epilepsy.

Precautions: Lamictal (lamotrigine) should be used with caution in patients with the following conditions: severe hepatic impairment, severe renal impairment, severe respiratory disease, and patients who are receiving concomitant valproic acid (VPA), particularly in the absence of enzyme-inducing AEDs.

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DISCONTINUATION
Discontinuation due to an adverse event was considered as serious occurred in 2.2% of patients and volunteers who received LAMICTAL in the premarketing studies. Rash accounted for almost half of the discontinuations due to serious adverse experiences. More rapid initial titration dosing of LAMICTAL, and concomitant use of antiepileptic were associated with higher incidences of rash-related withdrawal in clinical studies (see WARNINGS; see also PRECAUTIONS, Skin-Related Events, Tables 3).

CONTROLLED CLINICAL STUDIES Table 4 enumerates adverse experiences that occurred with an incidence of 2% or greater in patients or volunteers receiving LAMICTAL during clinical studies. The adverse experiences are grouped under standardized event categories. Some grouping similar types of adverse experiences into a smaller number of standardized event categories.

Other Events Observed During Clinical Studies: During clinical testing, multiple doses of LAMICTAL were administered to 5301 patients and volunteers. The conditions and duration of exposure to LAMICTAL during these clinical studies varied greatly. Studies included monotherapy and placebo trials. A substantial proportion of the experiences reported in open, uncontrolled clinical studies. All adverse experiences associated with exposure to LAMICTAL were recorded by clinical investigators using their knowledge of their own choosing. Consequently, it is not possible to provide a meaningful estimate of the proportion of individuals experiencing adverse events without first grouping these adverse experiences into a smaller number of standardized event categories. Some grouping similar types of adverse experiences into a smaller number of standardized event categories.

Since the adverse experiences reported during treatment with LAMICTAL in combination with other antiepileptic drugs, they were not necessarily caused by LAMICTAL. The following adverse events have been reported on one or more occasions by at least 1% of patients and volunteers exposed to LAMICTAL in combination with other antiepileptic drugs, are not necessarily caused by LAMICTAL.

MUSCULO-SKELETAL

DIAGNOSTIC

NEUROUS

DOSAGE AND ADMINISTRATION

LAMICTAL Tablets 150 mg: Cream, scored, shield-shaped tablets engraved with “LAMICTAL” and “150”. Bottles of 60.

LAMICTAL Tablets 100 mg: Peach, scored, shield-shaped tablets engraved with “LAMICTAL” and “100”. Bottles of 100.

LAMICTAL Tablets 25 mg: White, scored, shield-shaped tablets engraved with “LAMICTAL” and “25”. Bottles of 100.

Additional LAMICTAL (lamotrigine) is available for oral administration as an antiepileptic drug to supplement the antiepileptic therapy with other antiepileptic drugs in patients with treatment-resistant partial seizures. Epilepsia 1990;7(2):136-145.17. MatsuoFelal PlacerjoonMed study ol the effxacy

1. Treatment may be escalated at the discretion of the clinician, with a maximum dose of 50 mg once daily.

2. Patients in these studies were receiving 1 to 3 concomitant enzyme-inducing antiepileptic drugs in addition to LAMICTAL. In combination with other antiepileptic drugs, the patients were not necessarily caused by LAMICTAL. The following adverse events have been reported on one or more occasions by at least 1% of patients and volunteers exposed to LAMICTAL in combination with other antiepileptic drugs, are not necessarily caused by LAMICTAL. The following adverse events were reported on one or more occasions by at least 1% of patients and volunteers exposed to LAMICTAL in combination with other antiepileptic drugs, are not necessarily caused by LAMICTAL.