

Issued: 1 June 2009, Research Triangle Park, NC

FDA approves Lamictal[®]XR[™]; an extended-release once-daily, new generation treatment for epilepsy

GlaxoSmithKline (NYSE: GSK) announced today that the U.S. Food and Drug Administration has approved Lamictal[®]XR[™] (lamotrigine) Extended-Release Tablets as once-a-day add-on therapy for epilepsy patients 13 years of age or older with partial onset seizures. *Lamictal XR* reduced seizures in patients who were inadequately controlled on current therapy.

Lamictal XR reduced the frequency of partial seizures during a 19-week study. More patients who took *Lamictal XR* had a significant reduction in seizure frequency compared with placebo. These results were statistically significant. Patients enrolled in the study were inadequately controlled on one or two antiepileptic drugs. In fact, half of these patients were inadequately controlled on two antiepileptic drugs.

“Many patients require multiple doses of one or more medications to control their epilepsy, which makes taking their medicines even more challenging,” said Dean Naritoku, M.D., Professor and Chairman of Neurology, University of South Alabama, Mobile, AL. “*Lamictal XR* is an important once-daily advance for patients with epilepsy who still experience seizures while taking their current therapy.”

Lamictal XR is approved as add-on therapy for adult and adolescent patients who experience partial seizures with or without secondary generalization. Partial seizures, which are limited to one part of the brain, are the most common type of seizure experienced by people with epilepsy. Partial seizures may sometimes spread to affect the entire brain, an occurrence classified as secondary generalization. The safety and effectiveness of *Lamictal XR* have not been established in patients under the age of 13.

Patients with partial seizures currently taking immediate-release *Lamictal* twice-daily can be converted directly to once-a-day *Lamictal XR* using the same total daily dose. *Lamictal XR* will be available in pharmacies this summer.

Patented GlaxoSmithKline Extended-Release Technology

Lamictal XR Extended-Release Tablets are enteric-coated and contain a modified release formulation in the center of the tablet. There is a specially designed opening in the enteric coating on both sides of the tablet that utilizes a new technology called DiffCORE[™], discovered and developed by GlaxoSmithKline. This allows a controlled release of the medicine in the acidic environment of the stomach, leading to a gradual release of lamotrigine into the bloodstream.

Safety Information

Prescription *Lamictal XR* (lamotrigine) *Extended-Release Tablets* are not for everyone. *Lamictal XR* may cause a serious skin rash that may cause the patient to be hospitalized or to stop

Lamictal XR; it may rarely cause death. There is no way to tell if a mild rash will develop into a more serious reaction. These serious skin reactions are more likely to happen when the patient begins taking *Lamictal XR*, within the first two to eight weeks of treatment. But it can happen in people who have taken *Lamictal XR* for any period of time. Children between two to 16 years of age have a higher chance of getting this serious skin reaction while taking lamotrigine. *Lamictal XR* is not approved for use in children less than 13 years old.

The risk of getting a rash is higher if taking *Lamictal XR* while taking valproate (Depakene® (valproic acid) or Depakote® (divalproex sodium)), taking a higher starting dose of *Lamictal XR* than a healthcare provider prescribed or increasing the dose of *Lamictal XR* faster than prescribed.

Lamictal XR can also cause other types of allergic reactions or serious problems which may affect organs and other parts of your body like the liver or blood cells. The patient may or may not have a rash with these types of reactions.

The patient should call their healthcare provider right away if they have any of the following: a skin rash, hives, fever, swollen lymph glands, painful sores in the mouth or around the eyes, swelling of the lips or tongue, yellowing of the skin or eyes, unusual bruising or bleeding, severe fatigue or weakness, severe muscle pain or frequent infections. These symptoms may be the first signs of a serious reaction. A healthcare provider should examine the patient to decide if they should continue taking *Lamictal XR*.

Antiepileptic drugs, including *Lamictal XR*, increase the risk of suicidal thoughts or behavior in patients taking these drugs for any indication. Patients treated with any antiepileptic drug for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, or any unusual changes in mood or behavior.

Patients, their caregivers, and families should be informed that antiepileptic drugs increase the risk of suicidal thoughts and behavior and should be advised of the need to be alert for the emergence or worsening of the signs and symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts about self-harm. Behaviors of concern should be reported immediately to healthcare providers.

Medication errors involving *Lamictal* have occurred. In particular, the name *Lamictal* or lamotrigine can be confused with the names of other commonly used medications. Medication errors may also occur between the different formulations of *Lamictal*. To reduce the potential of medication errors, healthcare professionals should write and say *Lamictal XR* clearly. Depictions of the *Lamictal XR* can be found in the Medication Guide. To avoid the medication error of using the wrong drug or formulation, patients should be strongly advised to visually inspect their tablets to verify that they are *Lamictal XR* each time they fill their prescription.

Patients should not take *Lamictal XR* if they have had an allergic reaction to lamotrigine or to any of the inactive ingredients.

Common side effects of *Lamictal XR* include dizziness, diarrhea, weakness and fatigue, difficulty with coordination or balance, tremor, hot flashes, double vision, nausea, depression, muscle ache, and nervousness. Other common side effects that have been reported with another form of *Lamictal* include headache, sleepiness, and vomiting. Patients should tell their healthcare provider about any side effect that bothers them or does not go away; patients should tell their healthcare provider if they have any changes in their menstrual pattern, such as breakthrough bleeding, while taking *Lamictal XR* and birth control pills. These are not all the possible side effects of *Lamictal XR*.

For full prescribing information for *Lamictal XR*, including Boxed Warning, please visit www.gsk.com.

Editors' Note: About the Studies

FDA approval of *Lamictal XR* (lamotrigine) was based on data from the ARMOR study, an international, multi-center, randomized, double-blind, placebo-controlled trial of 236 patients 13 years of age or older with inadequately controlled partial seizures, who were taking a stable regimen of one or two antiepileptic drugs (AEDs) and experienced eight or more partial seizures during the eight-week baseline phase of the study. Patients in the baseline period were experiencing four to six seizures per week prior to being randomized to either *Lamictal XR* or placebo. The treatment period of the study consisted of a seven-week Escalation Phase and a 12-week Maintenance Phase.

Study results showed that the new once-daily, extended-release formulation of *Lamictal XR* reduced partial seizures by 47 percent, compared to 25 percent with placebo over the entire 19-week treatment period (P=0.0001).

A second study, COMPASS, was an open-label study evaluating the conversion from the immediate-release form of *Lamictal* given twice daily to the same total daily dose of *Lamictal XR* given once daily in 44 patients 13 years or older with epilepsy. Patients enrolled in the study were divided into three treatment groups based on the type of adjunctive antiepileptic drug they were taking. The rate at which *Lamictal* clears the bloodstream varies depending upon the other antiepileptic drugs a patient may be taking at the same time. The study results from COMPASS showed that patients could be switched from the immediate-release formulation of *Lamictal* taken twice daily to the same total daily dose of *Lamictal XR* taken once daily while maintaining comparable minimum blood levels of lamotrigine, regardless of the other antiepileptic medicines being taken concurrently.

The most common adverse events in the ARMOR study are presented above in the About *Lamictal XR* section. The most common drug-related adverse event in the COMPASS study was headache. No serious rashes were observed in either treatment group in both the ARMOR and COMPASS studies. However, the risk of serious rash caused by *Lamictal XR* is not expected to differ from that of with the immediate-release formulation of *Lamictal*. The prescribing information for *Lamictal XR* contains a boxed warning on serious rash that is further described in the About *Lamictal XR* section above.

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

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