



**Mebaral® (mephobarbital tablets, USP)**  
***Additional Product Discontinuation Information***

Lundbeck is aware of the difficult situation that some patients may face with regard to the discontinuation of Mebaral. The company thoroughly evaluated all avenues for keeping Mebaral available to patients, but ultimately concluded that no matter what steps we took, patients would be forced to transition to a new therapy.

Mebaral became available for use in this country in 1935 before the New Drug Application (NDA) process was implemented via the 1962 amendments to the Federal Food, Drug and Cosmetic Act. In 2010, Lundbeck learned that a New Drug Application (NDA) would be required to continue making Mebaral available. There were a number of factors that made it impossible for the company to secure regulatory approval in a timeframe that would enable patients to continue on the therapy without disruption. Gathering sufficient evidence to support an NDA submission and gain FDA approval is a complex process which in this situation would take at least 5 years to complete, and would force those on Mebaral to transition to another therapy despite the company's best efforts.

Lundbeck's remaining Mebaral inventory has a March 2012 expiration date, and we are no longer able to support product deliveries. We appreciate the fact that this development may put patients in a difficult position, especially among those who received Mebaral for many years. With that in mind, we first communicated this situation in January 2011. In addition to posting information online and communicating with patient and professional organizations, the company sent a letter to a list of almost 2,000 physicians that recently prescribed Mebaral, and sent another letter to the same list of physicians in September 2011. Beginning in January 2012, Lundbeck contacted each of these physician's offices via telephone to further inform of the discontinuation and to encourage the transition of Mebaral patients to other therapies. Through March 15, 2012, Lundbeck fulfilled emergency orders through a specialty pharmacy providing patients with transition product to get them through the March 31 expiration date.

Lundbeck makes several therapies available to people with challenging seizure disorders, and is aware of the ongoing struggles many physicians and their patients experience in managing their seizures. We are deeply committed to the epilepsy community, and sincerely regret the difficulty this situation has brought some patients.