

INsightAlert



Shire to Withdraw Brand ProAmatine®

On August 17, 2010 Shire Development Inc. announced that it will remove the drug ProAmatine from the market **effective September 30, 2010**. ProAmatine is used to treat the low blood pressure condition, orthostatic hypotension.

On August 16, 2010 the U.S. Food and Drug Administration proposed to withdrawal approval of the drug because required post-approval studies that verify the clinical benefit of the drug have not been done. The drug was approved in 1996 under the FDA's accelerated approval regulations for drugs that treat serious or life-threatening diseases. That approval required that the manufacturer verify clinical benefit to patients through post-approval studies.

Since its original approval, ProAmatine has also become available in generic formulations. Makers of the generic versions of the drug were given 30 days to respond to the FDA proposal. To date, neither Shire (the original manufacturer) nor any of the manufacturers of the generic version (midodrine) have provided evidence to confirm the drug's benefit.

As of the date of this notification, this withdrawal announcement only pertains to brand ProAmatine. As updated news is released regarding the status of generic midodrine products, the information will be disseminated accordingly.

Shire stated that the decision to remove the drug is not related to any concerns regarding safety of ProAmatine. Moreover, the reasoning is due to the fact that the drug isn't profitable enough to justify the additional clinical tests U.S. regulators are demanding to maintain its marketing authorization.

Members currently taking ProAmatine should contact their doctor to discuss appropriate alternative treatments. Any decision about which medication to take should be made by the physician based on individual patient needs.

The FDA is working with the drug manufacturers to develop an expanded-access program to allow patients who currently receive the drug to continue to receive it. On a case-by-case basis, expanded-access programs allow the use of a drug outside of a clinical trial to treat patients with a serious or immediately life-threatening disease or a condition that has no comparable or satisfactory alternative treatment options.

In response to this event, FutureScripts/FutureScripts Secure will:

- Post a point-of-sale (POS) message to retail pharmacists. Claims for ProAmatine prescriptions will reject at the point of sale with the following message: “NDC NOT ON FILE”.
- Send letters to all members who have filled a prescription for ProAmatine in the past six months, informing them of the withdrawal and of the need to contact their physician.
- Send letters to all physicians, identifying all members under their care who have filled a prescription for ProAmatine in the past six months, informing them of the recall and their options.
- Electronically distribute an FS INsight Alert to our clients
- Post a Web Alert for our members and providers