FDA Approves New Patch For Depression

Ed. Note: *The following is a press release from the US Food & Drug Administration.*

February 28, 2006 --

The Food and Drug Administration today approved Emsam (selegiline), the first skin (transdermal) patch for use in treating major depression. The once a day patch works by delivering selegiline, a monoamine oxidase inhibitor or MAOI, through the skin and into the bloodstream. At its lowest strength, Emsam can be used without the dietary restrictions that are needed for all oral MAO inhibitors that are approved for treating major depression.

"Emsam provides a significant advance because at least in its lowest dose patients can use the drug without the usual dietary restrictions associated with these types of drugs known as MAO inhibitors," said Dr. Steven Galson, Director for the Center for Drug Evaluation and Research.

Major depressive disorder is a common psychiatric condition in the U.S. population. Symptoms of depression include general emotional dejection, withdrawal and restlessness that interfere with daily functioning, such as loss of interest in usual activities; significant change in weight and/or appetite; insomnia; increased fatigue; feelings of guilt or worthlessness; slowed thinking or impaired concentration; and a suicide attempt or suicidal ideation.

MAO inhibitors usually require specific dietary restrictions because when combined with certain foods they can cause a sudden, large increase in blood pressure, or "hypertensive crisis". A hypertensive crisis can lead to a stroke and death. Symptoms of a hypertensive crisis include sudden onset of severe headache, nausea, stiff neck, a fast heartbeat or a change in the way your heart beats (palpitations), sweating, and confusion. Patients who have these symptoms should get medical care right away.

The lowest dose of the MAOI patch, which delivers 6 milligrams (mg) of the medication over a 24 hour period, can be used without such dietary restrictions.

The Emsam patch will be made available in three sizes that deliver 6, 9, or 12 mg of selegiline per 24 hours. The patch is a matrix containing three layers consisting of a backing, and adhesive drug layer, and a release liner that is placed against the skin.

Emsam has been shown safe and effective for treatment of major depressive disorder in two 6-8 week studies and also in a longer-term study of patients. The data for EMSAM 6mg/24hr support the recommendation that a modified diet is not required at this dose. Patients are advised to change the patch once a day. The more limited data available for EMSAM 9mg/24hr and 12mg/24hr do not rule out food effects so that patients receiving these higher doses should follow dietary restrictions that advise them to avoid certain foods or beverages. This includes foods and beverages such as aged cheese and wine.

The only common side effect of Emsam detected in placebo-controlled trials was a mild skin reaction where the patch is placed. There may be mild redness at the site when a patch is removed. If the redness does not go away within several hours after removing the patch or if irritation or itching continues, patients are advised to contact their doctor.

Another side effect that was seen less commonly was light-headedness related to a drop in blood pressure.

The manufacturer and distributor of this new product have planned an educational campaign for patients and prescribers to ensure that advice on dietary modifications for the higher patch strengths is adhered to. They plan to conduct both patient and health care provider surveys to assess the effectiveness of the educational campaign. The manufacturer and distributor will also closely track reports of adverse events, and follow-up on those that might represent hypertensive crises, to further ensure the safe use of this product.

Although the effects of heat on the patch are not known, the drug labeling advises health care professionals and patients about the possible effects of direct heat applied to the Emsam patch. Direct heat may result in an increased amount of the drug absorbed from the patch. Patients should avoid exposing the patch to heating pads, electric blankets, heat lamps, saunas, hot tubs, or prolonged sunlight.

Like all approved antidepressants, this product carries a warning of increased suicidality in children and adolescents.

EMSAM was developed by Somerset Pharmaceuticals, Inc. In December 2004, Bristol-Myers Squibb and Somerset entered into an agreement that provides Bristol-Myers Squibb with distribution rights to market EMSAM after approval in the United States. Selegiline was initially approved in capsule form for use in Parkinson's Disease.

Consumer Inquiries: 888-INFO-FDA