

May 31, 2006

## **Emsam® (Selegiline Transdermal System)**

### **DESCRIPTION**

Selegiline transdermal system (STS; Emsam®) is a monoamine oxidase (MAO) type-B inhibitor approved Feb. 28, 2006, as the first transdermal patch for the treatment of major depressive disorder. STS is available in three sizes, delivering 6 mg, 9 mg and 12 mg per 24 hours.

### **WHAT THE PHARMACIST SHOULD KNOW**

Selegiline HCl is currently approved, without dietary restrictions, at oral doses of 10 mg/day as an adjunct to levodopa in the management of late-stage Parkinson's disease and has been shown to have antidepressant activity at 30 to 60 mg/day. At these doses, the selectivity for MAO-B is lost, resulting in increased cardiovascular sensitivity to tyramine due to MAO-A inhibition, necessitating dietary restriction. STS has pharmacodynamic and pharmacokinetic advantages over oral selegiline, leading to greater CNS MAO-A and MAO-B inhibition and less inhibition of intestinal and liver MAO-A. However, only the lowest dose (6 mg/24 hr) has been shown to be safe without the use of dietary restriction of foods rich in tyramine. The recommended initial and target dose is one 6 mg/24 hr patch daily. The only adverse effects different from placebo included application site reactions and lightheadedness due to a drop in blood pressure.

### **WHAT YOU MAY NOT BE TOLD**

The more limited data available for STS 9 mg/24 hr and 12 mg/24 hr do not rule out food effects, so patients receiving these higher doses should follow dietary restrictions that advise them to avoid certain foods or beverages. It is uncertain whether the 9 mg or 12 mg strengths are more effective than the 6 mg strength. The only two major studies assessing transdermal selegiline for the treatment of major depressive disorder only took place for six to eight weeks. There are no long-term randomized controlled trials examining the safety and efficacy of the drug.

### **WHAT THE PATIENT SHOULD KNOW**

STS should be applied to dry, smooth skin on your upper chest or back, upper thigh, or the outer surface of the upper arm. Be sure to remove the old patch before applying the new patch – wear only one patch at a time. Change the patch at the same time everyday while rotating patch sites to minimize the risk of application site reactions. After applying the patch, wash your hands. After removing the old patch, throw it away out of the reach of children or pets. If you begin to feel like your depression is getting worse or if you begin to have suicidal thoughts, please contact your physician immediately. Be sure to tell everyone participating in your care all of your current medications, and indicate that you are taking an MAO-I. In addition, do not take any over-the-counter medications or herbals that have a WARNING label describing possible interactions with MAO-Is. It is advisable to avoid foods and drinks with high tyramine content, especially if you are taking the 9mg/24hr or 12 mg/24 hr patches. Consuming tyramine with an MAO-I may lead to an unsafe increase in your blood pressure. Additional information can be found at <http://www.bms.com/products/data/>.

### **HOW DOES THIS MEDICATION COMPARE TO OTHERS IN THE CLASS?**

This medication is the only MAO-B inhibitor indicated for the treatment of major depressive disorder. Other MAO inhibitors have fallen out of favor due to dietary restrictions of tyramine because of the risk of causing hypertensive crisis.

### **HOW DOES THIS MEDICATION COMPARE TO OTHERS FOR THE DISEASE STATE?**

STS provides the convenience of once-a-day transdermal application. However, most SSRIs are taken only once a day, so compliance should not be affected. There is a risk of suicide with the use of all antidepressants including STS.

Additional information is available at <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01326.html>.



**TYPICAL PATIENT QUESTIONS**

**What foods/drinks are high in tyramine content?**

Type of Food and Drink	Tyramine-Rich Foods and Drinks to Avoid	Acceptable Foods and Drinks, Containing No or Little Tyramine
Meat, Poultry and Fish	<ul style="list-style-type: none"> <li>• Air dried, aged and fermented meats, sausages and salamis</li> <li>• Pickled herring</li> <li>• Any spoiled or improperly stored meat, poultry and fish. These are foods that have a change in color, odor, or become moldy.</li> <li>• Spoiled or improperly stored animal livers</li> </ul>	<ul style="list-style-type: none"> <li>• Fresh meat, poultry and fish, including fresh processed meats (such as lunch meats, hot dogs, breakfast sausage, and cooked sliced ham)</li> </ul>
Vegetables	<ul style="list-style-type: none"> <li>• Broad bean pods (fava bean pods)</li> </ul>	<ul style="list-style-type: none"> <li>• All other vegetables</li> </ul>
Dairy (milk products)	<ul style="list-style-type: none"> <li>• Aged cheeses</li> </ul>	<ul style="list-style-type: none"> <li>• Processed cheeses, mozzarella, ricotta cheese, cottage cheese, and yogurt</li> </ul>
Drinks	<ul style="list-style-type: none"> <li>• All tap beers, and other beers that have not been pasteurized</li> </ul>	<ul style="list-style-type: none"> <li>• As with other antidepressants, concomitant use of alcohol with EMSAM is not recommended. (Bottled and canned beers and wines contain little or no tyramine.)</li> </ul>
Other	<ul style="list-style-type: none"> <li>• Concentrated yeast extract (such as Marmite)</li> <li>• Sauerkraut</li> <li>• Most soybean products (including soy sauce and tofu)</li> <li>• Over-the-counter supplements containing tyramine</li> </ul>	<ul style="list-style-type: none"> <li>• Brewer's yeast, baker's yeast</li> <li>• Soy milk</li> <li>• Pizzas from commercial chain restaurants prepared with cheeses low in tyramine</li> </ul>

Adapted from K. I. Shulman, S. E. Walker. *Psychiatric Annals*. 2001; 31:378-384.

**If I want to take less drug, can I cut the patch in half?** No, you cannot and should not cut these patches. Only change your dose if instructed to do so by your physician. **How long will it take until I begin to feel effects from the drug?** It may take six to eight weeks before effects from the drug are noticed. **Can I take this medication with an SSRI (e.g. Prozac, Paxil, Zoloft, etc.)?** No, SSRIs are contraindicated with STS.

**COST AND INSURANCE COVERAGE CONSIDERATIONS**

Generic	Product	AWP Cost per 30 days
Selegiline Transdermal	Emsam	\$482
Phenelzine	Nardil	\$50
Tranylcypromine	Parnate	\$88
Fluoxetine	Prozac	\$15
Sertraline	Zoloft	\$90
Paroxetine	Paxil/Paxil CR	\$30/\$95
Escitalopram	Lexapro	\$78
Citalopram	Celexa	\$30

The insurance company will set the co-payment, which is determined by the formulary status of the medication. AWP is a cost to be used for relative comparisons only and is not reflective of actual cost.

**DISCLAIMER**

This publication is intended to provide key practical information regarding this drug product in a brief format. It does not contain sufficient information upon which to base formulary or other medication use policy decisions.

