

MEDICATION GUIDE

EMSAM® [EM sam]

Generic Name: selegiline transdermal system

Rx only

Read this Medication Guide carefully before you start using EMSAM and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about EMSAM, ask your doctor or pharmacist.

IMPORTANT: Be sure to read the section of this Medication Guide beginning with “What is the most important information I should know about EMSAM?” It contains important information about certain changes in diet that might be needed, other medications to avoid, and other important information about this medication. It immediately follows the next section called Antidepressant Medicines, Depression and other Serious Mental Illnesses, and Suicidal Thoughts or Actions.

Antidepressant Medicines, Depression and other Serious Mental Illnesses, and Suicidal Thoughts or Actions

Read the Medication Guide that comes with you or your family member’s antidepressant medicine. This section of the Medication Guide is only about the risk of suicidal thoughts and actions with antidepressant medicines. **Talk to your, or your family member’s, healthcare provider about:**

- all risks and benefits of treatment with antidepressant medicines
- all treatment choices for depression or other serious mental illnesses

What is the most important information I should know about antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions?

1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.
2. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions. These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.
3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?
 - Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
 - Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
 - Keep all follow-up visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

What else do I need to know about antidepressant medicines?

- **Never stop an antidepressant medicine without first talking to a healthcare provider.** Stopping an antidepressant medicine suddenly can cause other symptoms.

- **Antidepressants are medicines used to treat depression and other illnesses.** It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- **Antidepressant medicines have other side effects.** Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- **Antidepressant medicines can interact with other medicines.** Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- **Not all antidepressant medicines prescribed for children are FDA approved for use in children.** Talk to your child’s healthcare provider for more information.

ABOUT USING ANTIDEPRESSANTS IN CHILDREN AND TEENAGERS

EMSAM at any dose should not be used in children under the age of 12 years even when administered with dietary modifications. EMSAM is not approved for use in pediatric patients.

What is the most important information I should know about EMSAM?

1. EMSAM (selegiline transdermal system) contains a medicine called a monoamine oxidase inhibitor, also called a MAOI. MAOI medicines, including EMSAM, can cause a sudden, large increase in blood pressure (hypertensive crisis) if you eat foods and drinks that contain high amounts of tyramine. A hypertensive crisis can be a life-threatening condition. See “What are the possible side effects of EMSAM?” for signs and symptoms of a hypertensive crisis.
- EMSAM comes in three different doses and patch sizes:
 - a 6 mg/24 hours patch
 - a 9 mg/24 hours patch
 - a 12 mg/24 hours patch
- You must avoid (not eat or drink) certain foods and drinks while using EMSAM 9 mg/24 hours and EMSAM 12 mg/24 hours patches and for 2 weeks after stopping EMSAM 9 mg/24 hours and EMSAM 12 mg/24 hours patches. (The table below lists these foods and drinks.¹) The table also lists foods and drinks that are okay to eat and drink while using EMSAM 9 mg/24 hours and EMSAM 12 mg/24 hours patches.
- You do not have to make any diet changes with the EMSAM 6 mg/24 hours patch.

Type of Food and Drink	Tyramine-Rich Foods and Drinks to Avoid	Acceptable Foods and Drinks, Containing No or Little Tyramine
<u>Meat, Poultry, and Fish</u>	<ul style="list-style-type: none"> • Air dried, aged and fermented meats, sausages and salamis • Pickled herring • Any spoiled or improperly stored meat, poultry, and fish. These are foods that have a change in color, odor, or become moldy. • Spoiled or improperly stored animal livers 	<ul style="list-style-type: none"> • Fresh meat, poultry, and fish, including fresh processed meats (such as lunch meats, hot dogs, breakfast sausage, and cooked sliced ham)
<u>Vegetables</u>	<ul style="list-style-type: none"> • Broad bean pods (fava bean pods) 	<ul style="list-style-type: none"> • All other vegetables
<u>Dairy (milk products)</u>	<ul style="list-style-type: none"> • Aged cheeses 	<ul style="list-style-type: none"> • Processed cheeses, mozzarella, ricotta cheese, cottage cheese, and yogurt

continued

Type of Food and Drink	Tyramine-Rich Foods and Drinks to Avoid	Acceptable Foods and Drinks, Containing No or Little Tyramine
<u>Drinks</u>	<ul style="list-style-type: none"> All tap beers and other beers that have not been pasteurized 	<ul style="list-style-type: none"> As with other antidepressants, concomitant use of alcohol with EMSAM is not recommended. (Bottled and canned beers and wines contain little or no tyramine.)
<u>Other</u>	<ul style="list-style-type: none"> Concentrated yeast extract (such as Marmite) Sauerkraut Most soybean products (including soy sauce and tofu) Over-the-counter supplements containing tyramine 	<ul style="list-style-type: none"> Brewer's yeast, baker's yeast Soy milk Pizzas from commercial chain restaurants prepared with cheeses low in tyramine

¹Adapted from K. I. Shulman, S. E. Walker, *Psychiatric Annals* 2001; 31:378-384

- All foods you eat must be fresh or properly frozen.
 - Avoid foods when you do not know their storage conditions.
- 2. EMSAM can cause serious and potentially life-threatening reactions if used with certain other medicines. Do not take the following medicines while using EMSAM, and for 2 weeks after stopping EMSAM:**
- other medicines to treat depression (antidepressants) including other MAOI medicines
 - medicine which contains selegiline (such as Eldepryl®)
 - St. John's wort (a herbal supplement)
 - Demerol® (meperidine), or medicines that contain meperidine (a narcotic pain medicine) or the pain medicines tramadol, methadone, or propoxyphene
 - Tegretol® (carbamazepine), or other medicines that contain carbamazepine (a seizure medicine)
 - Trileptal® (oxcarbazepine), or other medicines that contain oxcarbazepine (a seizure medicine)
 - Cold or cough preparations that contain dextromethorphan
 - Flexeril® or other medicines that contain cyclobenzaprine (a medicine used to treat muscle spasms)
 - decongestant medicines, found in many products to treat cold symptoms
 - over-the-counter diet pills or herbal weight-loss products
 - any herbal or dietary supplement that contains tyramine
 - medicines called amphetamines, also called stimulants or "uppers"
 - BuSpar® (buspirone HCl), an anxiety medicine

Some of these medicines will have to be stopped for at least a week before you can start using EMSAM.

What is EMSAM?

EMSAM is a skin patch (transdermal system) used to treat major depression. The skin patch delivers the medicine through your skin and into your bloodstream.

EMSAM has not been studied for the treatment of depression in children under 18 years of age.

Who should not use EMSAM?

Do not use EMSAM (selegiline transdermal system) if you are:

- taking certain other medicines. See "What is the most important information I should know about EMSAM?"
- allergic to anything in EMSAM. See the end of this Medication Guide for a complete list of ingredients in EMSAM.

What should I tell my doctor before starting EMSAM?

Tell your doctor about all your medical conditions, including if you:

- have any heart problems
- have or had manic episodes (a mental condition that causes "high" moods)
- have or had seizures (convulsions or "fits")
- tend to get dizzy or faint
- are pregnant or planning to become pregnant. It is not known if EMSAM can harm your unborn baby.
- are breast-feeding. It is not known if EMSAM passes into your milk or if it can harm your baby.

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. **EMSAM can cause a serious and life-threatening reaction if used with certain other medicines.** See "What is the most important information I should know about EMSAM?"

Know the medicines you take. Keep a list of them with you to show your doctor and pharmacist. Do not take any new medicine while using EMSAM, and for 2 weeks after you stop using it, before talking with your doctor.

How should I use EMSAM?

See the end of this Medication Guide for "How to Use and Apply an EMSAM Patch".

- Use EMSAM exactly as prescribed by your doctor. **Use only one patch at a time.** Change the patch once a day (every 24 hours). Choose a time of day that works best for you.
- Your doctor will prescribe a dose of EMSAM (selegiline transdermal system) based on your condition. Your doctor may change your dose if needed.
- Talk to your doctor often about your condition. You may notice an improvement in your condition with EMSAM therapy after several weeks. **Do not stop or change your treatment with EMSAM without talking to your doctor.**
- Make sure you do not eat foods or drink beverages that contain high amounts of tyramine while using EMSAM 9 mg/24 hours or EMSAM 12 mg/24 hours patches, and for 2 weeks after you stop using them.**
- If you use more than one EMSAM patch at a time, remove EMSAM patches right away and call your doctor or local Poison Control Center.
- Avoid exposing the EMSAM application site to external sources of direct heat, such as heating pads or electric blankets, heat lamps, saunas, hot tubs, heated water beds, and prolonged direct sunlight.
- Tell your doctor if you plan to have surgery. Also, tell your surgeon that you take EMSAM. EMSAM should be stopped 10 days before you have elective surgery.

What should I avoid while using EMSAM?

- You must not eat foods or drink beverages that contain high amounts of tyramine while using EMSAM 9 mg/24 hours and 12 mg/24 hours patches.** You do not have to make any diet changes with the EMSAM 6 mg/24 hours patch. See "What is the most important information I should know about EMSAM?"
- Do not take other medicines while using EMSAM or for 2 weeks after you stop using it unless your doctor has told you it is okay.** See "What is the most important information I should know about EMSAM?"
- Do not drive or operate dangerous machinery until you know how EMSAM affects you.** EMSAM may reduce your judgment, ability to think, or coordination.
- Drinking alcoholic beverages is not recommended while using EMSAM.

What are the possible side effects of EMSAM?

EMSAM:

- can cause a sudden, large increase in blood pressure ("hypertensive crisis") if you eat certain foods and drinks during treatment. See

“What is the most important information I should know about EMSAM?” A hypertensive crisis can lead to stroke and death. Symptoms of a hypertensive crisis include the sudden onset of severe headache, nausea, stiff neck, a fast heartbeat or a change in the way your heart beats (palpitations), a lot of sweating, and confusion. **If you suddenly have these symptoms, get medical care right away.**

- can cause serious and potentially life-threatening reactions if used with certain other medicines. See “What is the most important information I should know about EMSAM?”
- may worsen your depression, give you suicidal thoughts, or cause unusual changes in behavior. Call your doctor right away if you feel worse with EMSAM.
- may cause a mental condition called mania or hypomania (mental condition which causes high moods) in people who have a history of mania.
- can cause low blood pressure. Lie down if you feel dizzy, faint, or light-headed. Change your position slowly if low blood pressure is a problem for you. Tell your doctor if you have these symptoms. You may need a lower dose of EMSAM.

The most common side effect of EMSAM is a skin reaction where the patch is placed. You may see mild redness at the site when a patch is removed. This redness should go away within several hours after removing the patch. If irritation or itching continues, tell your doctor.

These are not all the side effects of EMSAM. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store EMSAM?

- Store EMSAM at 20° to 25° C (68° to 77° F).
- Store EMSAM in its sealed pouch until use.
- **Keep EMSAM and all medicines out of the reach of children and away from pets.**

General information about EMSAM

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. Do not give EMSAM to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about EMSAM. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about EMSAM that is written for health professionals.

For more information, call 1-866-367-2678 or visit www.EMSAM.com

What are the ingredients in EMSAM?

Active Ingredient: Selegiline

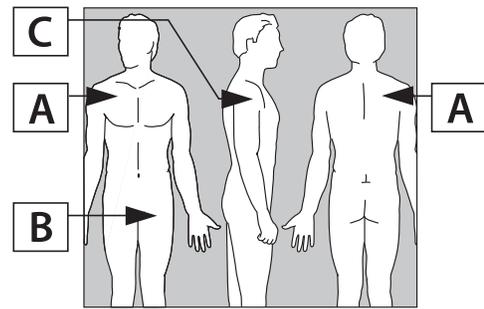
Inactive Ingredients: acrylic adhesive, ethylene vinyl acetate, polyethylene, polyester, polyurethane, and silicone coated polyester

How to Use and Apply an EMSAM Patch

Read these instructions carefully before you apply EMSAM (selegiline transdermal system). Ask your doctor or pharmacist about anything you do not understand.

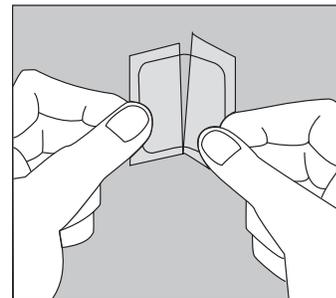
- Apply a new EMSAM patch every day (24 hours).
- **Wear only one EMSAM patch at a time.** Wear one EMSAM patch all the time until it is time to apply a new one.
- Remove a used patch before applying a new one.
- Change the patch at the same time each day.
- Apply an EMSAM patch to dry, smooth skin on your (A) upper chest or back (below the neck and above the waist), (B) upper thigh, or (C) to the outer surface of the upper arm. Choose a new site each time you change your patch. Do not use the same site 2 days in a row. (See Picture 1 for

skin sites that may be used.)

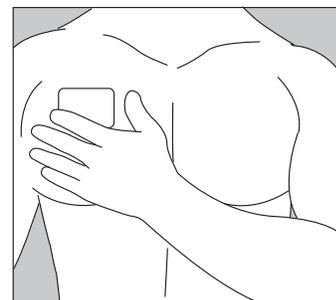


Picture 1. Skin sites for EMSAM patch. (Do not use more than one patch at a time.)

- Apply an EMSAM patch to an area of skin that is not hairy, oily, irritated, broken, scarred, or calloused. Do not place the patch where your clothing is tight, which could cause the patch to rub off.
- After you have selected the site for your patch, wash the area gently and well with soap and warm water. Rinse until all soap is removed. Dry the area with a clean dry towel.
- Just before you apply the patch, remove it from its sealed pouch. **Do not keep or store the patch outside of the sealed pouch. Never cut an EMSAM patch into smaller pieces to use.**
- Remove half of the protective backing and throw it away. (See Picture 2.) Try not to touch the exposed side (sticky side) of the patch, because the medicine could come off on your fingers. With your fingertips, press the sticky side of the patch firmly against the skin site that was just washed and dried. Remove the second half of the protective liner and press the remaining sticky side firmly against your skin. Make sure that the patch is flat against the skin (there should be no bumps or folds in the patch) and is sticking securely. Be sure the edges are stuck to the skin surface. (See Picture 3.)



Picture 2. Removing the protective backing from an EMSAM patch.



Picture 3. Applying an EMSAM patch.

- After you have applied the patch, wash your hands well with soap and water to remove any medicine that may have gotten on them. **Do not**

touch your eyes until after you have washed your hands.

- After 24 hours, remove the patch slowly and carefully to avoid damaging the skin. Do not touch the sticky side. As soon as you have removed the patch, fold it so that the sticky side sticks to itself.
- Throw away the folded patch so that children and pets cannot reach it. This patch still contains some medicine and could harm a child or pet.
- Gently wash the old application site with warm water and a mild soap to remove any sticky material (adhesive) that stays on your skin after removing the patch. A small amount of baby oil may also be used to remove any adhesive. You may need to use a medical adhesive removal pad that you can get from your pharmacist. Alcohol or other dissolving liquids such as nail polish remover may cause skin irritation and should not be used.
- Wash your hands with soap and water.
- If the patch becomes loose, press it back in place. If your **EMSAM** (selegiline transdermal system) patch falls off, apply a new **EMSAM** patch to a new site and resume your normal schedule for changing patches.
- If you forget to change your patch after 24 hours, remove the old patch, put on a new patch in a different area and continue to follow your original schedule.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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