

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 “About Using Antidepressants in Children and Teenagers.”

ABOUT USING ANTIDEPRESSANTS IN CHILDREN AND TEENAGERS

What is the most important information I should know if my child is being prescribed an antidepressant?

Parents or guardians need to think about 4 important things when their child is prescribed an antidepressant:

1. There is a risk of suicidal thoughts or actions
2. How to try to prevent suicidal thoughts or actions in your child
3. You should watch for certain signs if your child is taking an antidepressant
4. There are benefits and risks when using antidepressants

1. There is a Risk of Suicidal Thoughts or Actions

Children and teenagers sometimes think about suicide, and many report trying to kill themselves.

Antidepressants increase suicidal thoughts and actions in some children and teenagers. But suicidal thoughts and actions can also be caused by depression, a serious medical condition that is commonly treated with antidepressants. Thinking about killing yourself or trying to kill yourself is called *suicidality* or *being suicidal*.

A large study combined the results of 24 different studies of children and teenagers with depression or other illnesses. In these studies, patients took either a placebo (sugar pill) or an antidepressant for 1 to 4 months. ***No one committed suicide in these studies***, but some patients became suicidal. On sugar pills, 2 out of every 100 became suicidal. On the antidepressants, 4 out of every 100 patients became suicidal.

For some children and teenagers, the risks of suicidal actions may be especially high. These include patients with

- Bipolar illness (sometimes called manic-depressive illness)
- A family history of bipolar illness
- A personal or family history of attempting suicide

If any of these are present, make sure you tell your healthcare provider before your child takes an antidepressant.

2. How to Try to Prevent Suicidal Thoughts and Actions

To try to prevent suicidal thoughts and actions in your child, pay close attention to changes in her or his moods or actions, especially if the changes occur suddenly. Other important people in your child's life can help by paying attention as well (e.g., your child, brothers and sisters, teachers, and other important people). The changes to look out for are listed in Section 3, on what to watch for.

Whenever an antidepressant is started or its dose is changed, pay close attention to your child.

After starting an antidepressant, your child should generally see his or her healthcare provider:

- Once a week for the first 4 weeks
- Every 2 weeks for the next 4 weeks
- After taking the antidepressant for 12 weeks
- After 12 weeks, follow your healthcare provider's advice about how often to come back
- More often if problems or questions arise (see Section 3)

You should call your child's healthcare provider between visits if needed.

3. You Should Watch for Certain Signs If Your Child is Taking an Antidepressant

Contact your child's healthcare provider *right away* if your child exhibits any of the following signs for the first time, or if they seem worse, or worry you, your child, or your child's teacher:

- Thoughts about suicide or dying
- Attempts to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling very agitated or restless
- Panic attacks
- Difficulty sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry, or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking
- Other unusual changes in behavior or mood

Never let your child stop taking an antidepressant without first talking to his or her healthcare provider. Stopping an antidepressant suddenly can cause other symptoms.

4. There are Benefits and Risks When Using Antidepressants

Antidepressants are used to treat depression and other illnesses. Depression and other illnesses can lead to suicide. In some children and teenagers, treatment with an antidepressant increases suicidal thinking or actions. It is important to discuss all the risks of treating depression and also the risks of not treating it. You and your child should discuss all treatment choices with your healthcare provider, not just the use of antidepressants.

Other side effects can occur with antidepressants (see section below).

Of all the antidepressants, only fluoxetine (Prozac®) has been FDA approved to treat pediatric depression.

For obsessive compulsive disorder in children and teenagers, the FDA has approved only fluoxetine (Prozac®), sertraline (Zoloft®), fluvoxamine (Luvox®), and clomipramine (Anafranil®).

Your healthcare provider may suggest other antidepressants based on the past experience of your child or other family members.

Is this all I need to know if my child is being prescribed an antidepressant?

No. This is a warning about the risk for suicidality. Other side effects can occur with antidepressants.

Be sure to ask your healthcare provider to explain all the side effects of the particular drug he or she is prescribing. Also ask about drugs to avoid when taking an antidepressant. Ask your healthcare provider or pharmacist where to find more information.

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

1. **EMSAM 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 6mg/24hours patch
 - a 9mg/24hours patch
 - a 12mg/24hours patch
 - **You must avoid (not eat or drink) certain foods and drinks while using EMSAM 9mg/24hours and EMSAM 12mg/24hours patches and for 2 weeks after stopping EMSAM 9mg/24hours and EMSAM 12mg/24hours patches. (The table below lists these foods and drinks). The table also lists foods and drinks that are okay to eat and drink while using EMSAM 9mg/24hours and EMSAM 12mg/24hours patches.**
 - **You do not have to make any diet changes with the EMSAM 6mg/24hours patch.**

<i>Type of Food and Drink</i>	<i>Tyramine-Rich Foods and Drinks to Avoid</i>	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 • and any spoiled or improperly stored meat, poultry and fish. These are foods that have a change in color, odor, or become moldy. 	<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)

	<ul style="list-style-type: none"> spoiled or improperly stored animal livers. 	
<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
<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, bakers yeast Soy milk Pizzas from commercial chain-restaurants prepared with cheeses low in tyramine.

¹ Adapted 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 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 breastfeeding.** 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** 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 9mg/24hours or EMSAM 12mg/24hours 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 9mg/24hours and 12mg/24hours patches.** You do not have to make any diet changes with the EMSAM 6 mg/24hours 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 lightheaded. 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.

How do I store EMSAM?

- Store **EMSAM** at 68° to 77°F (20° to 25°C).
- 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 1-800-321-1335 or visit www.EMSAM.com

What are the ingredients in EMSAM?

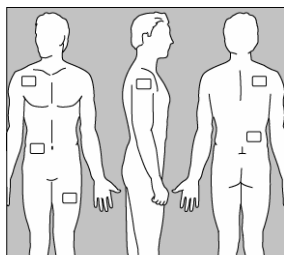
Active Ingredient: Selegiline

Inactive Ingredients: acrylic adhesive, ethylene vinyl acetate, low density polyethylene, polyester, polyurethane, and silicon coated polyethylene terephthalate

How to Use and Apply an EMSAM Patch

Read these instructions carefully before you apply EMSAM. Ask your doctor or pharmacist about anything you do not understand.

- Apply a new **EMSAM** patch every day (24hours).
- **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 upper chest or back (below the neck and above the waist), upper thigh or to the outer surface of the upper arm. Choose a new site each time you change your patch. Do not use the same site two days in a row. (See picture 1 for skin sites that may be used.)

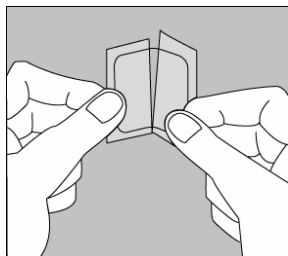


Picture 1. Skin sites for EMSAM patch (Do not use more than one patch at a time)

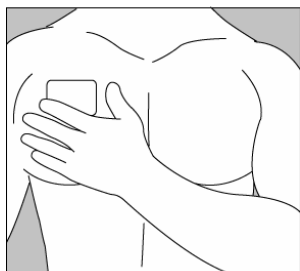
- Apply an EMSAM patch to an area of skin that is not hairy, oily, irritated, broken, scarred or calloused. Do not place the patch where your clothing is tight, which could cause the patch to rub

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

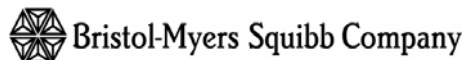
After you have applied the patch, wash your hands well with soap and water to remove any medicine that may have gotten on them. **Do not touch your eyes until after you have washed your hands.**

- 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 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 US Food and Drug Administration.

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