

Remeron (mirtazapine)

FDA ALERT [07/2005] Suicidal Thoughts or Actions in Children and Adults

Patients with depression or other mental illnesses often think about or attempt suicide. Closely watch anyone taking antidepressants, especially early in treatment or when the dose is changed. Patients who become irritable or anxious, or have new or increased thoughts of suicide or other changes in mood or behavior (or their care givers) should contact their healthcare professional right away.

Children

Taking antidepressants may increase suicidal thoughts and actions in about 1 out of 50 people 18 years or younger. Although mirtazapine is prescribed for children, FDA has not approved mirtazapine for use in children.

Adults

Several recent scientific publications report the possibility of an increased risk for suicidal behavior in adults who are being treated with antidepressant medications. Even before these reports became available, FDA began a complete review of all available data to determine whether there is an increased risk of suicidal thinking or behavior in adults being treated with antidepressant medications. It is expected that this review will take a year or longer to complete. In the meantime, FDA is highlighting that adults being treated with antidepressant medication, particularly those being treated for depression, should be watched closely for worsening of depression and for increased suicidal thinking or behavior.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information.

Brand and Generic Names:

- Brand names = Remeron[®], Remeron SolTab

Tablets and Orally Disintegrating Tablets: 15 mg, 30 mg, and 45 mg

- Generic name = mirtazapine

What is Remeron[®] and what does it treat?

Mirtazapine is an antidepressant medication that works in the brain. It is approved for the treatment of Major Depressive Disorder (MDD). Major Depression occurs when a person experiences several of the following symptoms concurrently, for at least two weeks: "low" or depressed mood (for example, sad, empty, tearful); decreased interest in most or all activities; changes in appetite (usually decreased); changes in sleep (usually poor sleep); loss of energy; feeling worthless/guilty/ hopeless/ helpless; psychomotor agitation or retardation (i.e. thoughts/movements speeding up or slowing down); difficulty concentrating, and thoughts of death (suicidal thinking).

What is the most important information I should know about Remeron[®]?

After starting mirtazapine, symptoms gradually decrease over a period of weeks. Sleep and other physical symptoms may improve before there is noticeable improvement in mood or interest in activities. Once symptoms are under control, MDD usually requires long-term treatment to help prevent the return of depressive symptoms. Only your healthcare provider can determine the length of generic name treatment that is right for you.

Do not stop taking mirtazapine or change your dose without talking to with your healthcare provider first.

Because depression is also a part of Bipolar illness, people who take antidepressants may be at risk for "switching" from depression into mania. Symptoms of mania include "high" or irritable mood, very high self esteem, decreased need for sleep, pressure to keep talking, racing thoughts, being easily distracted, frequently involved in activities with a large risk for bad consequences (for example, excessive buying sprees).

Are there specific concerns about Remeron[®] and pregnancy?

If you are planning on becoming pregnant, notify your healthcare provider so that he/she can best manage your medications. People living with MDD who wish to become pregnant face important decisions, each with risks and benefits. This is a complex decision as untreated MDD or depression relapse may have negative consequences for both the fetus and the mother. There are many dimensions to these choices, so be sure to confer with your doctor and caregivers.

The FDA has classified mirtazapine as a Category C pregnancy risk. This means that animal reproduction studies have demonstrated adverse effects of mirtazapine on the fetus, however there are no well-controlled studies in humans. Additionally, the benefits from use of bupropion may be acceptable despite potential risks.

Women who discontinue medication therapy are up to five times more likely to have a depression relapse than those who continue their antidepressant. Untreated depression or depression relapse may have negative consequences for both the fetus and the mother. If you are pregnant, please discuss the risks and benefits of this medication use with your healthcare provider.

Regarding breast-feeding, caution is advised since mirtazapine does pass into breast milk.

What should I discuss with my healthcare provider before taking Remeron®?

- The most bothersome symptoms of your condition
- If you have thoughts of suicide
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- Any medical problems that you may have especially kidney disease
- All other medications you are currently taking and any medication allergies you have
- If you are pregnant, plan to become pregnant, or are breast-feeding
- If you drink alcohol or use drugs

How should I take Remeron®?

Mirtazapine is usually taken once a day at bedtime with or without food.

While the dose usually ranges from 15 mg to 45 mg, your healthcare provider will determine the dose that is right for you based upon your response.

What happens if I miss a dose of Remeron®?

If you miss a dose of mirtazapine, take it as soon as you remember unless it is close to when your next dose is due. If you missed a dose of medication and it is close to the time of your next dose, skip the missed dose and take your next dose at the regularly scheduled time. Do not double your next dose or take more than your prescribed dose.

What should I avoid while taking Remeron®?

Avoid drinking alcohol or using illegal drugs while you are taking antidepressant medications because the beneficial effects of the medication may be decreased and adverse effects may be increased (e.g. sedation, dizziness).

What happens if I overdose with Remeron®?

If an overdose occurs, whether intentional or accidental, immediate medical attention may be necessary. Call your doctor or emergency medical service (911). You may also contact the poison control center (1-800-222-1222).

Symptoms of overdose include disorientation, drowsiness, memory problems, and fast heart rate. A specific antidote does not exist.

What are the possible side effects of Remeron®?

Side effects with mirtazapine are generally mild and often resolve over the first 1-2 weeks of treatment as you continue to take the medication. The most commonly reported side effects are drowsiness, increased appetite, weight gain and increased triglycerides. Agranulocytosis (low white blood cell count) is a rare but serious side effect that occurs in less than 1% of patients. Since the introduction of **mirtazapine** in the U.S. in 1997, agranulocytosis has not been a problem and most scientists now believe it is not a specific side effect of mirtazapine.

Unlike many SSRIs, mirtazapine does not commonly cause sexual dysfunction and may be selected as an alternative treatment when antidepressant-induced sexual dysfunction is problematic.

Are there any risks for taking Remeron® for long periods of time?

To date, there are no known problems associated with long term use of mirtazapine. It is a safe and effective medication when used as directed.

What other drugs may interact with Remeron®?

Mirtazapine should not be taken with or within two weeks of taking monoamine oxidase inhibitors (MAOIs). These include phenelzine (Nardil®), tranylcypromine (Parnate®), isocarboxazid (Marplan®) and selegeline (Emsam®).

If you take clonidine for high blood pressure, starting mirtazapine may cause a significant increase in blood pressure.

Although rare, there is an increased risk of serotonin syndrome when mirtazapine is used with other medications that increase serotonin such as other antidepressants, migraine medications called “triptans” (e.g. Imitrex®) and the analgesic tramadol (Ultram®).

Always let your doctor know what other prescription, over-the-counter, and herbal medications you are taking.

How long does it take for Remeron® to work?

While depressed mood and lack of interest in activities may need up to 4-6 weeks to improve, disturbances in sleep, energy, or appetite may show some improvement within the first 1-2 weeks. Improvement in these physical symptoms can be an important early signal that the medication is working.

*Updated by
Glen L. Stimmel, Pharm.D., BCPP
(March 2007)*



NAMI wishes to thank the [College of Psychiatric and Neurological Pharmacists](#) for producing this fact sheet.

Reviewed by Dr. Ken Duckworth, NAMI Medical Director

For further information please contact the pharmaceutical company listed below.

Organon	375 Mt. Pleasant Ave. West Orange, NJ 07052	800-631-1253	www.organon.com
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Free or low-cost medications provided by pharmaceutical companies

Some pharmaceutical companies offer medication assistance programs to low-income individuals and families. These programs typically require a doctor's consent and proof of financial status. They may also require that you have either no health insurance, or no prescription drug benefit through your health insurance. Please contact the pharmaceutical company directly for specific eligibility requirements and application information.

Remeron Rx Assistance Program: 1-800-241-8812