



Patient Information Sheet

Mirtazapine (marketed as Remeron)

5/2007: The suicidal thoughts or actions in children and adults issue has been addressed in product labeling.

Please see: <http://www.fda.gov/cder/drug/antidepressants/default.htm>

This is a summary of the most important information about mirtazapine. For detailed information, talk to your healthcare professional.

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. FDA intends to update this sheet when additional information or analyses become available.

What Is Mirtazapine?

- Mirtazapine is a medicine that is used to treat depression.

Who Should Not Take Mirtazapine?

Never take mirtazapine if you are taking another drug used to treat depression, called a Monoamine Oxidase Inhibitor (MAOI), or if you have stopped taking a MAOI in the last 14 days. Taking mirtazapine close in time to an MAOI can result in serious, sometimes fatal, reactions, including:

- High body temperature
- Coma
- Seizures (convulsions)

MAOI drugs include Nardil (phenelzine sulfate), Parnate (tranylcypromine sulfate), Marplan (isocarboxazid), and other brands.

What Are The Risks?

- **Suicidal Thoughts or Actions:** See FDA Alert.
- **Agranulocytosis.** Mirtazapine may cause agranulocytosis, which is a very low number of a type white blood cells that are needed to fight infection. Call your healthcare professional if you get a fever, sore throat, mouth sores, or other signs of infection.
- **Severe sleepiness causing impaired judgement, thinking, and motor skills:** Do not drive a car or operate dangerous machines until you know how mirtazapine affects you.
- **Dizziness**
- **Increased appetite and weight gain**
- **Increases in cholesterol, triglycerides and liver function tests**
- **Mania:** You may become hyperactive, excitable, or elated.
- **Seizures.** You may experience a seizure (convulsion), even if you are not taking mirtazapine close in time with a MAOI.
- **Sexual problems:** You may have problems with impotence (erectile dysfunction), abnormal ejaculation, difficulty reaching orgasm, or decreased libido (sexual desire).
- **Do not drink alcohol.** Alcohol can increase the impaired judgement, thinking, and motor skills that happen with mirtazapine.
- **Other side effects** include sleepiness, nausea, increased appetite, weight gain, and dizziness
- **Tell your healthcare professional** about all your medical conditions, especially if you have heart problems, kidney or liver problems, mania, or had a heart attack or stroke. Tell your healthcare professional if you are pregnant or plan to become pregnant. Tell your healthcare





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professional if you are breast-feeding or plan to breast-feed your baby.

Are There Any Interactions With Drugs Or Foods?

Mirtazapine may interact with medicines other than the ones already mentioned in this information sheet, causing serious side effects. Tell your healthcare professional about all the medicines, vitamins, and herbal supplements you take, especially Valium (diazepam) or other anti-anxiety or sleeping medicines.

How Do I Take Mirtazapine?

- Mirtazapine is taken by mouth, with or without food, exactly as prescribed by your healthcare professional.
- Mirtazapine orally disintegrating tablets will melt on your tongue. Do not break or split mirtazapine orally disintegrating Tablets.

Is There Anything Else I Need To Know?

You can get more information about antidepressants at:

<http://www.fda.gov/cder/drug/antidepressants/default.htm>

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