

MEDICATION GUIDE
REMERON® (rĕm' - ě - rŏn)
(mirtazapine)
Tablets

What is the most important information I should know about REMERON®?

REMERON and other antidepressant medicines may cause serious side effects, including:

1. Suicidal thoughts or actions:

- **REMERON and other antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, or young adults within the first few months of treatment or when the dose is changed.**
- Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.
- Watch for these changes and call your healthcare provider right away if you notice:
 - New or sudden changes in mood, behavior, actions, thoughts, or feelings, especially if severe.
 - Pay particular attention to such changes when REMERON is started or when the dose is changed.

Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency, especially if they are new, worse, or worry you:

- attempts to commit suicide
- acting on dangerous impulses
- acting aggressive or violent
- thoughts about suicide or dying
- new or worse depression
- new or worse anxiety or panic attacks
- feeling agitated, restless, angry or irritable
- trouble sleeping
- an increase in activity or talking more than what is normal for you
- other unusual changes in behavior or mood

Call your healthcare provider right away if you have any of the following symptoms, or call 911 if an emergency.

REMERON may be associated with these serious side effects:

2. Manic episodes:

- greatly increased energy
- reckless behavior
- talking more or faster than usual
- severe trouble sleeping
- unusually grand ideas
- racing thoughts
- excessive happiness or irritability

3. Decreased White Blood Cells called neutrophils, which are needed to fight infections. Tell your doctor if you have any indication of infection such as fever, chills, sore throat, or mouth or nose sores, especially symptoms which are flu-like.

4. Serotonin Syndrome. This condition can be life-threatening and may include:

- agitation, hallucinations, coma or other changes in mental status
- racing heartbeat, high or low blood pressure
- nausea, vomiting, or diarrhea
- coordination problems or muscle twitching (overactive reflexes)
- sweating or fever
- muscle rigidity

5. Visual problems

- eye pain
- changes in vision
- swelling or redness in or around the eye

Only some people are at risk for these problems. You may want to undergo an eye examination to see if you are at risk and receive preventative treatment if you are.

6. Seizures

7. Low salt (sodium) levels in the blood.

Elderly people may be at greater risk for this. Symptoms may include:

- headache
- confusion, problems concentrating or thinking or memory problems
- weakness or feeling unsteady

8. Sleepiness. It is best to take **REMERON** close to bedtime.

9. Severe skin reactions: Call your doctor right away if you have any or all of the following symptoms:

- severe rash with skin swelling (including on the palms of the hands and soles of the feet)
- painful reddening of the skin, blisters, or ulcers on the body or in the mouth

10. Severe allergic reactions: trouble breathing, swelling of the face, tongue, eyes or mouth

- rash, itchy welts (hives) or blisters, alone or with fever or joint pain

11. Increases in appetite or weight. Children and adolescents should have height and weight monitored during treatment.

12. Increased cholesterol and triglyceride levels in your blood

Do not stop REMERON without first talking to your healthcare provider. Stopping REMERON too quickly may cause potentially serious symptoms including:

- dizziness
- abnormal dreams
- agitation
- anxiety
- fatigue
- confusion
- headache
- shaking
- tingling sensation
- nausea, vomiting
- sweating

What is REMERON?

REMERON is a prescription medicine used to treat depression. It is important to talk with your healthcare provider about the

risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your healthcare provider.

Talk to your healthcare provider if you do not think that your condition is getting better with REMERON treatment.

Who should not take REMERON?

Do not take REMERON:

- if you are allergic to mirtazapine or any of the ingredients in REMERON. See the end of this Medication Guide for a complete list of ingredients in REMERON.
- if you take a monoamine oxidase inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid.
- Do not take an MAOI within 2 weeks of stopping REMERON unless directed to do so by your healthcare provider.
- Do not start REMERON if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.

People who take REMERON close in time to an MAOI may have serious or even life-threatening side effects. Get medical help right away if you have any of these symptoms:

- | | | |
|---|------------------------------|------------------------------------|
| ○ high fever | ○ uncontrolled muscle spasms | ○ stiff muscles |
| ○ rapid changes in heart rate or blood pressure | ○ confusion | ○ loss of consciousness (pass out) |

What should I tell my healthcare provider before taking REMERON?

Before you take REMERON, tell your healthcare provider about all of your medical conditions, including if you:

- are taking certain drugs such as:
 - Triptans used to treat migraine headache
 - Medicines used to treat mood, anxiety, psychotic or thought disorders, including tricyclics, lithium, SSRIs, SNRIs, or antipsychotics
 - Tramadol used to treat pain
 - Over-the-counter supplements such as tryptophan or St. John's wort
 - Phenytoin, carbamazepine, or rifampicin (these drugs can decrease your blood level of REMERON)
 - Cimetidine or ketoconazole (these drugs can increase your blood level of REMERON)
 - Medicines that may affect your hearts rhythm (such as certain antibiotics and some antipsychotics)
- have or had:
 - liver problems
 - kidney problems
 - heart problems or certain conditions that may change your heart rhythm
 - seizures or convulsions
 - bipolar disorder or mania
 - a tendency to get dizzy or faint
- are pregnant or plan to become pregnant. It is not known if REMERON will harm your unborn baby. Talk to your healthcare provider about the benefits and risks of treating depression during pregnancy
- are breastfeeding or plan to breastfeed. Some REMERON may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking REMERON

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. REMERON and some medicines may interact with each other, may not work as well, or may cause serious side effects.

Your healthcare provider or pharmacist can tell you if it is safe to take REMERON with your other medicines. Do not start or stop any medicine while taking REMERON without talking to your healthcare provider first. If you take REMERON, you should not take any other medicines that contain mirtazapine including REMERONSolTab®.

How should I take REMERON?

- Take REMERON exactly as prescribed. Your healthcare provider may need to change the dose of REMERON until it is the right dose for you.
- Take REMERON at the same time each day, preferably in the evening at bedtime.
- Swallow REMERON as directed.
- It is common for antidepressant medicines such as REMERON to take up to a few weeks before you start to feel better. Do not stop taking REMERON if you do not feel results right away.
- Do not stop taking or change the dose of REMERON without first talking to your doctor, even if you feel better.
- REMERON may be taken with or without food.
- If you miss a dose of REMERON, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of REMERON at the same time.
- **If you take too much REMERON**, call your healthcare provider or poison control center right away, or get emergency treatment. The signs of an overdose of REMERON (without other medicines or alcohol) include:
 - confusion,
 - memory problems
 - drowsiness
 - increased heart rate.

The symptoms of a possible overdose may include changes to your heart rhythm (fast, irregular heartbeat) or fainting, which could be symptoms of a life-threatening condition known as Torsades de Pointes.

What should I avoid while taking REMERON?

- REMERON can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how REMERON affects you.
- Avoid drinking alcohol or taking diazepam (a medicine used for anxiety, insomnia and seizures, for example) or similar medicines while taking REMERON. If you are uncertain about whether certain medication can be taken with REMERON, please discuss with your doctor.

What are the possible side effects of REMERON?

REMERON may cause serious side effects:

- See “What is the most important information I should know about REMERON?”

The most common side effects of REMERON include:

- sleepiness
- increased appetite
- weight gain
- abnormal dreams
- constipation
- dizziness
- dry mouth

These are not all the possible side effects of REMERON.

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

How should I store REMERON?

- Store REMERON at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep REMERON away from light.
- Keep REMERON bottle closed tightly.

Keep REMERON and all medicines out of the reach of children.

General information about the safe and effective use of REMERON.


Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use REMERON for a condition for which it was not prescribed. Do not give REMERON to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about REMERON that is written for healthcare professionals.

What are the ingredients in REMERON?

Active ingredient: mirtazapine

Inactive ingredients:

- **15 mg tablets:** Starch (corn), hydroxypropyl cellulose, magnesium stearate, colloidal silicon dioxide, lactose, hypromellose, polyethylene glycol 8000, titanium dioxide, ferric oxide (yellow).
- **30 mg tablets:** Starch (corn), hydroxypropyl cellulose, magnesium stearate, colloidal silicon dioxide, lactose, hypromellose, polyethylene glycol 8000, titanium dioxide, ferric oxide (yellow), ferric oxide (red).
- **45 mg tablets:** Starch (corn), hydroxypropyl cellulose, magnesium stearate, colloidal silicon dioxide, lactose, hypromellose, polyethylene glycol 8000, titanium dioxide.

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For more information about REMERON call 1-800-526-4099 or go to www.REMERON.com.

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

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