

Medication Guide
REMERONSoTab® (rĕm' - ě - rŏn - sŏl' – tăb)
(mirtazapine)
Orally Disintegrating Tablets

Read the Medication Guide that comes with REMERONSoTab before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about REMERONSoTab, talk to your healthcare provider.

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

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

1. Suicidal thoughts or actions:

- **REMERONSoTab 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 REMERONSoTab 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. REMERONSoTab may be associated with these serious side effects:

2. Manic episodes:

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

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

- coordination problems or muscle twitching (overactive reflexes)
- racing heartbeat, high or low blood pressure
- sweating or fever
- nausea, vomiting, or diarrhea
- muscle rigidity

5. Seizures

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

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

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

7. Sleepiness. It is best to take **REMERONSolTab** close to bedtime.

8. 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 and/or blisters/ulcers on the body or in the mouth

9. 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

10. Increases in appetite or weight.

Children and adolescents should have height and weight monitored during treatment.

11. Increased cholesterol and triglyceride levels in your blood

Do not stop REMERONSolTab without first talking to your healthcare provider.

Stopping REMERONSolTab too quickly may cause potentially serious symptoms including:

- dizziness
- abnormal dreams
- agitation
- anxiety
- fatigue
- confusion

- headache
- shaking
- tingling sensation
- nausea, vomiting
- sweating

What is REMERONSolTab?

REMERONSolTab 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 REMERONSolTab treatment.

Who should not take REMERONSolTab?

Do not take REMERONSolTab if you:

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

People who take REMERONSolTab 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 REMERONSolTab?

Ask if you are not sure.

Before starting REMERONSolTab, tell your healthcare provider 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 REMERONSolTab)
 - Cimetidine or ketoconazole (these drugs can increase your blood level of REMERONSolTab)
- Have or had:
 - liver problems
 - kidney problems
 - heart problems
 - 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 REMERONSolTab 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 REMERONSolTab may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking REMERONSolTab

Tell your healthcare provider about all the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. REMERONSolTab 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 REMERONSolTab with your other medicines. Do not start or stop any medicine while taking REMERONSolTab without talking to your healthcare provider first.

If you take REMERONSolTab, you should not take any other medicines that contain mirtazapine including REMERON Tablets.

How should I take REMERONSolTab?

- Take REMERONSolTab exactly as prescribed. Your healthcare provider may need to change the dose of REMERONSolTab until it is the right dose for you.
- Take REMERONSolTab at the same time each day, preferably in the evening at bedtime.
- Open the tablet blister pack with dry hands and place the tablet whole on the tongue, immediately after removal from the blister pack.
- REMERONSolTab will disintegrate rapidly on the tongue and can be swallowed with saliva. No water is needed for taking it.
- Do not attempt to split the REMERONSolTab.
- It is common for antidepressant medicines such as REMERONSolTab to take up to a few weeks before you start to feel better. Do not stop taking REMERONSolTab if you do not feel results right away.
- Do not stop taking or change the dose of REMERONSolTab without first talking to your doctor, even if you feel better.

- REMERONSolTab may be taken with or without food.
- If you miss a dose of REMERONSolTab, 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 REMERONSolTab at the same time.
- If you take too much REMERONSolTab, call your healthcare provider or poison control center right away, or get emergency treatment.

What should I avoid while taking REMERONSolTab?

- REMERONSolTab 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 REMERONSolTab affects you.
- Avoid drinking alcohol or taking diazepam (a medicine used for anxiety, insomnia and seizures, for example) or similar medicines while taking REMERONSolTab. If you are uncertain about whether certain medication can be taken with REMERONSolTab, please discuss with your doctor.

What are the possible side effects of REMERONSolTab?

REMERONSolTab may cause serious side effects, including all of those described in the section entitled "What is the most important information I should know about REMERONSolTab?"

Common possible side effects in people who take REMERONSolTab include:

- sleepiness
- increased appetite, weight gain
- dry mouth
- constipation
- dizziness

- abnormal dreams

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of REMERONSolTab. For more information, ask your healthcare provider or pharmacist.

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 REMERONSolTab?

- Store REMERONSolTab at room temperature 25°C (77°F). Storage at 15°C-30°C (59°F-86°F) is permitted occasionally.
- Keep REMERONSolTab away from light and moisture.
- Use immediately upon opening individual tablet blister.

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

General information about REMERONSolTab

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use REMERONSolTab for a condition for which it was not prescribed. Do not give REMERONSolTab to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about REMERONSolTab. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider or pharmacist for information about REMERONSolTab that is written for healthcare professionals.

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

What are the ingredients in REMERONSolTab?

Active ingredient: mirtazapine

Inactive ingredients 15mg, 30mg and 45mg tablets: Aspartame, citric acid anhydrous, crospovidone, magnesium stearate, mannitol, microcrystalline cellulose, natural and artificial orange flavor, sodium bicarbonate, hypromellose, povidone, sugar spheres, Eudragit E100.

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

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