MEDICATION GUIDE

Mirtazapine Tablets USP

Rx only

What is the most important information I should know about mirtazapine tablets USP?

Antidepressant Medicines, Depression and other Serious Mental Illnesses, and Suicidal Thoughts or Actions

Read the Medication Guide that comes with your or your family member's antidepressant medicine. This Medication Guide is only about the risk of suicidal thoughts and actions with antidepressant medicines.

Talk to your, or your family member's, healthcare provider about:

- all risks and benefits of treatment with antidepressant medicines
- all treatment choices for depression or other serious mental illness

What is the most important information I should know about antidepressant medicines, depression and other serious mental illnesses, and suicidal thoughts or actions?

1. Antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, and young adults within the first few months of treatment.
2. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a particularly high risk of having suicidal thoughts or actions. These include people who have (or have a family history of) bipolar illness (also called manicdepressive illness) or suicidal thoughts or actions.
3. How can I watch for and try to prevent suicidal thoughts and actions in myself or a family member?
   - Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is very important when an antidepressant medicine is started or when the dose is changed.
   - Call the healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
   - Keep all followup visits with the healthcare provider as scheduled. Call the healthcare provider between visits as needed, especially if you have concerns about symptoms.

Call a healthcare provider right away if you or your family member has any of the following symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

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

What else do I need to know about antidepressant medicines?

- Never stop an antidepressant medicine without first talking to a healthcare provider. Stopping an antidepressant medicine suddenly can cause other symptoms.
- Antidepressants are medicines used to treat depression and other illnesses. It is important to discuss all the risks of treating depression and also the risks of not treating it. Patients and their families or other caregivers should discuss all treatment choices with the healthcare provider, not just the use of antidepressants.
- Antidepressant medicines have other side effects. Talk to the healthcare provider about the side effects of the medicine prescribed for you or your family member.
- Antidepressant medicines can interact with other medicines. Know all of the medicines that you or your family member takes. Keep a list of all medicines to show the healthcare provider. Do not start new medicines without first checking with your healthcare provider.
- Not all antidepressant medicines prescribed for children are FDA approved for use in children. Talk to your child's healthcare provider for more information.

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

What are mirtazapine tablets USP?

Mirtazapine tablets USP are a prescription medicine used to treat depression.

Who should not take mirtazapine tablets USP?

Do not take mirtazapine tablets USP if you:

- are allergic to mirtazapine or any of the ingredients in mirtazapine tablets USP. See the end of the Medication Guide for a complete list of ingredients in mirtazapine tablets USP.
- currently take or have taken within the last 14 days, any medicine known as Monamine Oxidase Inhibitors (MAOI). Taking an MAOI with certain other medicines, with similar actions to mirtazapine tablets USP, can cause serious or even lifethreatening side effects.

What should I tell my doctor before taking mirtazapine tablets USP?
Tell your doctor about all your medical conditions, including if you:

- have or had liver problems
- have or had kidney problems
- have or had manic episodes
- have had a seizure (convulsion)
- have any heart problems
- tend to get dizzy or faint
- are pregnant or planning to become pregnant. It is not known if mirtazapine tablets USP will harm your unborn baby.
- are breastfeeding. It is not known if mirtazapine passes into your milk or if it can harm your unborn baby.

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. Mirtazapine tablets USP and some medicines may interact with each other and may not work as well, or cause possible serious side effects. Your doctor can tell you if it is safe to take mirtazapine tablets USP with your other medicines.

How should I take mirtazapine tablets USP?

- Take mirtazapine tablets USP exactly as prescribed by your doctor.
- Take mirtazapine tablets USP at the same time each day, preferably in the evening at bedtime.
- Swallow mirtazapine tablets USP as directed.
- It is common for antidepressant medicines such as mirtazapine tablets USP to take up to a few weeks before you start to feel better. Do not stop taking mirtazapine tablets USP if you do not feel results right away.
- Do not stop taking or change the dose of mirtazapine tablets USP without talking to your doctor, even if you feel better.
- If you miss a dose of mirtazapine tablets USP, do not take another dose to make up for the dose you forgot. Wait and take your tablet at the next regular time.
- If you take too much mirtazapine tablets USP, call your doctor or poison control center or go to the emergency room right away.

What should I avoid while taking mirtazapine tablets USP?

- Mirtazapine tablets USP can cause drowsiness, which 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 mirtazapine tablets USP affect you.
- Avoid drinking alcohol or taking diazepam (a medicine used for anxiety, insomnia and seizures, for example) or similar medicines, while taking mirtazapine tablets USP. If you are unsure about whether a certain medication can be taken together with mirtazapine tablets USP, please discuss this with your doctor.

What are the possible side effects of mirtazapine tablets USP?
Mirtazapine tablets USP may be associated with serious side effects, including:

- See the beginning of this Medication Guide Antidepressant Medicines, Depression and other Serious Mental Illnesses, and Suicidal Thoughts or Actions
- Serotonin Syndrome: This is a condition that can be life threatening. Call your doctor right away if you become severely ill and have some or all of these symptoms:
  - stiffness
  - muscle spasm
  - confusion
  - irritability
  - agitation
  - increased body temperature
  - fast heart rate
  - increased blood pressure
- 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 flulike.
- Increased cholesterol and triglyceride levels in your blood
- Symptoms when stopping mirtazapine tablets USP (discontinuation symptoms). Side effects may occur when stopping mirtazapine tablets USP (discontinuation symptoms), especially when therapy is stopped suddenly. Your healthcare provider may want to decrease your dose slowly to help avoid side effects. Some of these side effects may include:

- dizziness
- abnormal dreams
- agitation
- anxiety
- fatigue
- confusion
- headache
- shaking
- tingling sensation
- nausea
- vomiting
- sweating
- Mania
- Seizures
- Low sodium levels in your blood: Call your doctor right away if you become severely ill and have some or all of these symptoms:
- headache
- feel weak
- confusion
- problems concentrating
- memory problems
- feel unsteady

The most common side effects with mirtazapine tablets USP include: sleepiness, increased appetite, weight gain and dizziness.

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the possible side effects with mirtazapine tablets USP.

For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store mirtazapine tablets USP?

- Store at 20° to 25°C (68° to 77°F).
- Protect from light and moisture.

Keep mirtazapine tablets USP and all medicines out of the reach of children.

General information about mirtazapine tablets USP

- Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
- Do not use mirtazapine tablets USP for a condition for which they were not prescribed. Do not give mirtazapine tablets USP to other people, even if they have the same condition as you have. They may harm them.
- This Medication Guide summarizes the most important information about mirtazapine tablets USP. If you have any concerns or would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about mirtazapine tablets USP that is written for health professionals.

For more information, call 1-888-838-2872, MEDICAL AFFAIRS.

What are the ingredients in mirtazapine tablets USP?

Active ingredient: mirtazapine.
Inactive ingredients: colloidal silicon dioxide, corn starch, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol 400, povidone, and titanium dioxide. The 15 mg tablet also contains iron oxide yellow and polyethylene glycol 6000. The 30 mg tablet also contains iron oxide red, iron oxide yellow, and polyethylene glycol 6000.

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

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