MEDICATION GUIDE

Mirtazapine (mir taz' a peen)

Tablets USP

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

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

1. Suicidal thoughts or actions:

- **Mirtazapine tablets 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 mirtazapine tablets are 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. Mirtazapine tablets 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. 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
- weakness or feeling unsteady
- confusion, problems concentrating or thinking or memory problems

8. Sleepiness. It is best to take **mirtazapine tablets** 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 mirtazapine tablets without first talking to your healthcare provider. Stopping mirtazapine tablets too quickly may cause potentially serious symptoms including:

- dizziness
- abnormal dreams
- agitation

- anxiety
- fatigue
- confusion
- headache
- shaking
- tingling sensation
- nausea, vomiting
- sweating

What are mirtazapine tablets?

Mirtazapine tablets are 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 mirtazapine tablets treatment.

Who should not take mirtazapine tablets?

Do not take mirtazapine tablets:

- if you are allergic to mirtazapine or any of the ingredients in mirtazapine tablets. See the end of this Medication Guide for a complete list of ingredients in mirtazapine tablets.
- 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 mirtazapine tablets unless directed to do so by your healthcare provider.
- Do not start mirtazapine tablets if you stopped taking an MAOI in the last 2 weeks unless directed to do so by your healthcare provider.

People who take mirtazapine tablets 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 mirtazapine tablets?

Before you take mirtazapine tablets, 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 mirtazapine)
- Cimetidine or ketoconazole (these drugs can increase your blood level of mirtazapine)
- Medicines that may affect your heart's 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 mirtazapine tablets 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 mirtazapine may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby while taking mirtazapine tablets

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Mirtazapine tablets 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 mirtazapine tablets with your other medicines. Do not start or stop any medicine while taking mirtazapine tablets without talking to your healthcare provider first. If you take mirtazapine tablets, you should not take any other medicines that contain mirtazapine including mirtazapine orally disintegrating tablets.

How should I take mirtazapine tablets?

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

- Mirtazapine tablets 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 mirtazapine tablets 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. If you are uncertain about whether certain medication can be taken with mirtazapine tablets, please discuss with your doctor.

What are the possible side effects of mirtazapine tablets?

Mirtazapine tablets may cause serious side effects:

- See "What is the most important information I should know about mirtazapine tablets?"

The most common side effects of mirtazapine tablets include:

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

These are not all the possible side effects of mirtazapine tablets.

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 mirtazapine tablets?

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

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

General information about the safe and effective use of mirtazapine tablets.

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

For more information about mirtazapine tablets, call 1-888-838-2872.

What are the ingredients in mirtazapine tablets USP?

Active ingredient: mirtazapine, USP

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

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

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