

## MEDICATION GUIDE

### Mirtazapine Tablets, USP (mir taz' a peen)

Medication Guide available at [www1.apotex.com/products/us](http://www1.apotex.com/products/us)

**What is the most important information I should know about mirtazapine tablets? Mirtazapine tablets may cause serious side effects, including:**

- **Increased risk of suicidal thoughts or actions in some children and young adults.** Mirtazapine tablets, and other antidepressant medicines may increase suicidal thoughts or actions in some people 24 years of age and younger, **especially within the first few months of treatment or when the dose is changed. mirtazapine tablets are not for use in children.**
  - **Depression or other serious mental illnesses are the most important causes of suicidal thoughts or actions.**

**How can I watch for and try to prevent suicidal thoughts and actions?**

- Pay close attention to any changes, especially sudden changes in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions. This is very important when an antidepressant medicine is started or when the dose is changed.
- Call your healthcare provider right away to report new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

**Call your healthcare provider or get emergency medical help right away if you or your family member have any of the following symptoms, especially if they are new, worse, or worry you:**

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

**What are mirtazapine tablets?**

Mirtazapine tablets are prescription medicines used to treat a certain type of depression called Major Depressive Disorder (MDD) in adults.

It is not known if mirtazapine tablets are safe and effective for use to treat MDD in children.

**Who should not take mirtazapine tablets? Do not take mirtazapine tablets if you:**

- take a Monoamine Oxidase Inhibitor (MAOI)
- have stopped taking an MAOI in the last 14 days
- are being treated with the antibiotic linezolid or intravenous methylene blue
- 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

Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI, including the antibiotic linezolid or intravenous methylene blue.

**Do not start taking an MAOI for at least 14 days after you stop treatment with mirtazapine tablets. Before taking mirtazapine tablets, tell your healthcare provider about all your medical conditions, including if you:**

- have a history of suicide or depression

- have a history or family history of bipolar disorder, mania or hypomania
- have a low white blood cell count
- have glaucoma (high pressure in the eye)
- have or had heart problems or stroke
- have an abnormal heart beat called QT prolongation or a family history of QT prolongation
- have seizures
- have high cholesterol or triglyceride levels
- have low sodium levels in your blood
- have or had kidney or liver problems
- have low blood pressure
- are pregnant or plan to become pregnant. It is not known if mirtazapine tablets will harm your unborn baby.
  - Talk to your healthcare provider if you become pregnant or think you may be pregnant during treatment with mirtazapine tablets.
  - If you become pregnant while taking mirtazapine tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants. You can register by calling 1-844-405-6185 or visiting online at <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/>. The purpose of this registry is to monitor the pregnancy outcomes in women who have been treated with mirtazapine tablets at any time during pregnancy.
- are breastfeeding or plan to breastfeed. Mirtazapine may pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with mirtazapine tablets.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Mirtazapine tablets and other medicines may affect each other causing possible serious side effects. Mirtazapine tablets may affect the way other medicines work and other medicines may affect the way mirtazapine tablets work.

**Especially tell your healthcare provider if you take:**

- MAOIs
- medicines to treat migraine headaches known as triptans
- tricyclic antidepressants
- fentanyl
- lithium
- tramadol
- tryptophan
- buspirone
- amphetamines
- benzodiazepines
- St. John's Wort
- medicines used to treat mood, anxiety, psychotic or thought disorders, including selective serotonin reuptake inhibitors (SSRIs) and serotonin norepinephrine reuptake inhibitors (SNRIs)
- medicines that may affect your heart rhythm (such as certain antibiotics and some antipsychotics)

Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare provider can tell you if it is safe to take mirtazapine tablets with your other medicines.

Do not start or stop any other medicines during treatment with mirtazapine tablets without talking to your healthcare provider first. Stopping mirtazapine tablets suddenly may cause you to have serious side effects.

**See, "What are the possible side effects of mirtazapine tablets?"**

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

### How should I take mirtazapine tablets?

- Take mirtazapine tablets exactly as your healthcare provider tells you to. Do not change your dose or stop taking mirtazapine tablets without first talking to your healthcare provider.
- Your healthcare provider may need to change the dose of mirtazapine tablets until it is the right dose for you
- Take mirtazapine tablets 1 time each day, preferably in the evening at bedtime
- If you take too much mirtazapine tablets call your healthcare provider or poison control center at 1-800-222-1222 right away or go to the nearest hospital emergency room.

### What should I avoid while taking mirtazapine tablets?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how mirtazapine tablets affects you. Mirtazapine tablets can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly.
- Avoid drinking alcohol during treatment with mirtazapine tablets.
- Avoid taking medicines used to treat anxiety, insomnia, and seizures, called benzodiazepines, during treatment with mirtazapine tablets. Ask your healthcare provider if you are not sure if you take one of these medicines.

### What are the possible side effects of mirtazapine tablets?

#### Mirtazapine tablets may cause serious side effects, including:

- See, “**What is the most important information I should know about mirtazapine?**”
- **Low white blood cell count.** Tell your healthcare provider right away if you develop any signs or symptoms of a low white blood cell count, including:
  - fever
  - sore throat
  - flu-like symptoms
  - chills
  - mouth or nose sores
  - infections
- **Serotonin syndrome.** A potentially life-threatening problem called serotonin syndrome can happen when you take mirtazapine tablets with certain other medicines. See, “**Who should not take mirtazapine tablets?**” Stop taking mirtazapine tablets and call your healthcare provider or go to the nearest hospital emergency room right away if you have any of the following signs and symptoms of serotonin syndrome:
  - agitation
  - confusion
  - fast heart beat
  - dizziness
  - flushing
  - tremors, stiff muscles, or muscle twitching
  - seizures
  - seeing or hearing things that are not real (hallucinations)
  - coma
  - blood pressure changes
  - sweating
  - high body temperature (hyperthermia)
  - loss of coordination
  - nausea, vomiting, diarrhea
- **Eye problems (angle-closure glaucoma).** Mirtazapine tablets may cause a certain type of eye problem called angle-closure glaucoma. Call your healthcare provider if you have eye pain, changes in your vision, or 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.
- **Heart rhythm problems.**
- **Increased appetite and weight gain.**
- **Sleepiness.** See, “**What should I avoid while taking mirtazapine tablets?**”
- **Mania or hypomania (manic episodes)** in people who have a history of bipolar disorder. Symptoms may include:

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

- **Seizures (convulsions).**

- **Increased fat levels (cholesterol and triglycerides) in your blood.**

- **Low sodium levels in your blood (hyponatremia).** Low sodium levels in your blood may be serious and may cause death. Elderly people may be at greater risk for this. Signs and Symptoms of low sodium levels in your blood may include:

- o headache
- o memory changes
- o weakness and unsteadiness on your feet which can lead to falls
- o difficulty concentrating
- o confusion

**In severe or more sudden cases, signs and symptoms include:**

- o hallucinations (seeing or hearing things that are not real)
- o seizures
- o respiratory arrest
- o fainting
- o coma
- o death

- **Changes in liver function tests.**

- **Discontinuation syndrome.** Suddenly stopping mirtazapine tablets may cause you to have serious side effects. Your healthcare provider may want to decrease your dose slowly. Symptoms may include:

- o dizziness
- o irritability and agitation
- o anxiety
- o sweating
- o seizures
- o nausea and vomiting
- o problems sleeping
- o tiredness
- o confusion
- o electric shock sensation (paresthesia)
- o shaking (tremor)
- o headache
- o abnormal dreams
- o changes in your mood
- o hypomania

**The most common side effects of mirtazapine tablets include:**

- sleepiness
- increased appetite
- weight gain
- dizziness

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 FDA at 1-800-FDA-1088.

**How should I store mirtazapine tablets?**

- Store mirtazapine tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep mirtazapine tablets away from light and moisture.

**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 it was not prescribed. Do not give mirtazapine tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about mirtazapine tablets that is written for healthcare professionals.

**What are the ingredients in mirtazapine tablets?**

**Active ingredient:** mirtazapine

**Inactive ingredients:** Colloidal silicon dioxide anhydrous, corn starch, ferric oxide (yellow), hydroxypropyl cellulose, hypromellose, polyethylene glycol 8000, lactose monohydrate, magnesium stearate, and titanium dioxide. The 30 mg tablets also contain ferric oxide (red).

**APOTEX INC.  
MIRTAZAPINE TABLETS, USP  
15 mg, 30 mg and 45 mg**

**Manufactured by**  
Apotex Inc.  
Toronto, Ontario  
Canada M9L 1T9

**Manufactured for**  
Apotex Corp.  
Weston, Florida  
33326

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