

**Mirtazapine Cas No. : 61337-67-5**

Mirtazapine is used to treat depression. It improves mood and feelings of well-being. Mirtazapine is an antidepressant that works by restoring the balance of natural chemicals (neurotransmitters) in the brain.

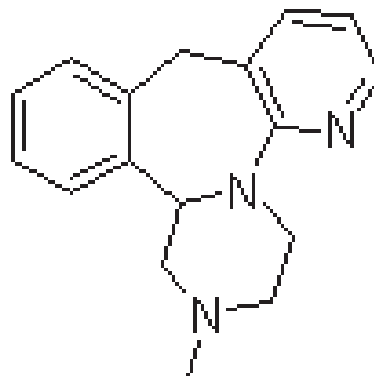
Active Pharmaceuticals Ingredients Manufacturers



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**Taj Pharmaceuticals Ltd.****Mirtazapine****CAS No. : 61337-67-5**

Molecular Formula C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>  
 Molecular Weight 265.35  
 CAS Number 61337-67-5  
 ATC code N06AX11  
 PubChem 4205  
 DrugBank DB00370  
 ChemSpider 4060

**Chemical data**

Formula C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>  
 Mol. mass 265.36

**Pharmacokinetic data**

Bioavailability 50%  
 Metabolism Liver  
 Half life 37 hours (females), 26 hours (males)  
 Excretion 75% urine 15% feces

**DOSAGE**

The usual starting dose for mirtazapine is 15 mg once daily, usually at bedtime. Doses may be increased every 1-2 weeks up to a maximum dose of 45 mg daily. It may be taken with or without food.

The tablets should be swallowed with at least half a glass of water whilst sitting or standing. This is to make sure that they reach the stomach and do not stick in the throat.

Take your medication as directed on the medicine label, usually once a day, at bedtime. Try to take it at a regular time each day. Taking it at mealtimes may make it easier to remember as there are no problems about taking this drug with or after food. Although you may take it at bedtime and it may help you sleep, mirtazapine is, however, not a sleeping tablet.

**SIDE EFFECTS**

All medicines may cause side effects, but many people have no, or minor, side effects most COMMON side effects persist or become bothersome: Abnormal dreams; abnormal thinking; constipation; dizziness; drowsiness; dry mouth; flu symptoms; increased appetite; weakness; weight gain. Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); decreased ability to fight infection (fever, chills, sore throat); mental or mood changes; mouth sores; thoughts of hurting yourself; tremors; worsening of depression.

**COMMON**

**Drowsiness** Feeling sleepy or sluggish. It can last for a few hours after taking your dose. This usually wears off after a week or so. Don't drive or use machinery. Ask your doctor if you can take your mirtazapine at a different time of day.

**Weight gain** A bigger appetite and putting on weight. A diet full of vegetables and fibre may help prevent weight gain. See also a separate question in this section. If you put on a lot of weight, you may need to switch to another antidepressant.



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**RARE**

Rashes and pruritis Rashes anywhere on the skin. These may be itchy. Stop taking and contact your doctor now.

**VERY RARE**

Agranulo-cytosis Low numbers of white cells in the blood. You may get more infections. Always tell your doctor or carer if you have any unexplained fever, chill, sore throat or mouth sores. You may need a blood test. See also a separate question in this section.

Information Associated with Product:

**PRECAUTIONS**

Tell your doctor your medical history, especially of: kidney problems, liver problems, other mental/mood conditions (e.g., bipolar disorder), seizures, heart disease, strokes, high cholesterol, any allergies. This drug may make you dizzy or drowsy; use caution engaging in activities requiring alertness such as driving or using machinery. Limit alcoholic beverages. To minimize dizziness and lightheadedness, get up slowly when rising from a seated or lying position.

Though uncommon, depression can lead to thoughts or attempts of suicide. Tell your doctor immediately if you have any suicidal thoughts, worsening depression, or any other mental/mood changes (including new or worsening anxiety, agitation, panic attacks, trouble sleeping, irritability, hostile/angry feelings, impulsive actions, severe restlessness, rapid speech). Keep all medical appointments so your healthcare professional can monitor your progress closely and adjust/change your medication if needed. Caution is advised when using this drug in the elderly because they may be more sensitive to the effects of the drug. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. If this medication is used during the last 3 months of pregnancy, infrequently your newborn may develop symptoms including feeding or breathing difficulties, seizures, muscle stiffness, jitteriness, or constant crying. However, do not stop taking this medication unless your doctor directs you to do so. Report any such symptoms to your doctor promptly. It is not known whether this drug passes into breast milk. Consult your doctor before breast-feeding.

A few people can gain weight on mirtazapine. If you have problems with your weight, your doctor can arrange for you to see a dietician for advice, or consider switching to another drug.

Drugs can affect desire (libido), arousal (erection) and orgasmic ability. Mirtazapine is not thought to have a significant effect on any of these.

You should avoid alcohol while taking these drugs as it may make you feel more sleepy. This is particularly important if you need to drive or operate machinery and you must seek advice on this.

You should have no problems with any food or drink other than alcohol.

**INTERACTION**

Use of mirtazapine with antidepressants referred to as monoamine oxidase inhibitors such as tranylcypromine and phenelzine

is strongly prohibited due to the potential for high fever, muscle stiffness, sudden muscle spasms, rapid changes in heart rate and blood pressure, and the possibility of death. In fact, there should be a lapse of at least 14 days between taking an MAOI and mirtazapine.

Because mirtazapine may cause drowsiness, it should be used carefully with other medications that also make people prone to sleepiness, such as antidepressants, antipsychotics, antihistamines, anti-anxiety agents, and alcohol.



Increased sleepiness has been reported when mirtazapine was used with both alcohol and the anti-anxiety drug diazepam.

#### DRUG DESCRIPTION

Mirtazapine is an antidepressant used for the treatment of moderate to severe depression.

Mirtazapine is a white to creamy white crystalline powder which is slightly soluble in water.

Mirtazapine is in a class of medications called tetracyclic antidepressants that includes maprotiline (Ludiomil). Although the precise mechanism of action of this class of antidepressants is not known, they increase the amount of norepinephrine and serotonin in the brain. Norepinephrine and serotonin are neurotransmitters, chemicals that nerves use to communicate with each other. Mirtazapine also acts as an antihistamine similar to diphenhydramine

Mirtazapine is best known for treating depression. However, it may also be used for treating anxiety or to make people drowsy just before surgery.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:  
91 022 30601000.

This leaflet was prepared by  
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