

Mirtazapine Sandoz®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Mirtazapine Sandoz?

Mirtazapine Sandoz contains the active ingredient mirtazapine. Mirtazapine Sandoz is used to treat depression.

For more information, see Section [1. Why am I using Mirtazapine Sandoz?](#) in the full CMI.

2. What should I know before I use Mirtazapine Sandoz?

Do not use if you have ever had an allergic reaction to Mirtazapine Sandoz or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Mirtazapine Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Mirtazapine Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Mirtazapine Sandoz?

- The usual starting dose is 15 mg per day. Your doctor may slowly increase this dose depending on how you respond to Mirtazapine Sandoz.
- The effective dose for most people is usually between 30 mg and 45 mg per day.

More instructions can be found in Section [4. How do I use Mirtazapine Sandoz?](#) in the full CMI.

5. What should I know while using Mirtazapine Sandoz?

Things you should do	• Remind any doctor, dentist, or pharmacist you visit that you are using Mirtazapine Sandoz. • If you have any suicidal thoughts or other mental/mood changes, tell your doctor immediately or go to the nearest hospital for treatment. • Tell your doctor if you feel the tablets are not helping your condition.
Things you should not do	• Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	• Do not drive or operate machinery until you know how Mirtazapine Sandoz affects you. • This medicine may cause drowsiness, dizziness or sleepiness in some people and affect alertness and concentration.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Keep your medicine in the original container. • Store tablets below 25°C.

For more information, see Section [5. What should I know while using Mirtazapine Sandoz?](#) in the full CMI.

6. Are there any side effects?

Common side effects: lethargy, drowsiness, or sleepiness, headache, tiredness, dry mouth, diarrhoea, constipation, increase in appetite and weight gain, nausea, vomiting, **Serious side effects:** skin rashes, itching or hives; swelling of the face, lips, or tongue which may cause difficulty breathing, severe skin reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Mirtazapine Sandoz®

Active ingredient(s): *mirtazapine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Mirtazapine Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mirtazapine Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Mirtazapine Sandoz?](#)
- [2. What should I know before I use Mirtazapine Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Mirtazapine Sandoz?](#)
- [5. What should I know while using Mirtazapine Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Mirtazapine Sandoz?

Mirtazapine Sandoz contains the active ingredient mirtazapine. This medicine corrects this chemical imbalance and may help relieve the symptoms of depression.

Mirtazapine Sandoz is used to treat depression. Depression is longer lasting or more severe than "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

2. What should I know before I use Mirtazapine Sandoz?

Warnings

Do not use Mirtazapine Sandoz if:

- you are allergic to mirtazapine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
Some of the symptoms of an allergic reaction may include:
 - skin rash, itching or hives,
 - swelling of the face, lips, mouth, throat, or other parts of the body,
 - shortness of breath,
 - wheezing or difficulty breathing.

- you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking an MAOI within the last 14 days. If you stop taking Mirtazapine Sandoz, do not take MAOI during the next two weeks either.
 - Examples of MAOIs include phenelzine, tranylcypromine and selegiline. Taking this medicine with a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Check with your doctor if you:

- have any other medical conditions
 - thoughts of suicide or self-harm
 - epilepsy (fits or convulsions)
 - liver disease such as jaundice
 - kidney disease
 - heart disease
 - low blood pressure (hypotension)
 - certain kinds of heart conditions that may change your heart rhythm, a recent heart attack, heart failure, or take certain medicines that may affect the heart's rhythm.
 - any mental illness (e.g. schizophrenia, manic depression)
 - diabetes
 - glaucoma (increased pressure in your eyes)
 - problems in urinating due to an enlarged prostate
 - unexplainable high fever, sore throat, or mouth ulcers
 - galactose intolerance
 - glucose-galactose malabsorption.
- take any medicines for any other condition
- react badly to lactose or milk before you start taking Mirtazapine Sandoz. Mirtazapine Sandoz tablets contain lactose.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take Mirtazapine Sandoz if you are pregnant or intend to become pregnant.

Tell your doctor if you become pregnant while taking this medicine. Do not stop taking your tablets until you have spoken to your doctor.

Like most medicines of this kind, this medicine is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of taking this medicine when pregnant.

If you use Mirtazapine Sandoz until, or shortly before birth, your baby should be supervised for possible adverse effects.

Do not take Mirtazapine Sandoz if you are breastfeeding or intend to breastfeed.

It is not known whether this medicine passes into breast milk.

Use in Children

Do not give this medicine to a child or adolescent. The safety of this medicine in patients under 18 years has not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with Mirtazapine Sandoz and affect how it works. These include:

- other medicines (e.g., SSRIs, venlafaxine, L-tryptophan, nefazodone) for depression, anxiety, obsessive compulsive disorders or pre-menstrual dysphoric disorder
- monoamine oxidase inhibitors (MAOIs) such as tranylcypromine, phenelzine and selegiline
- medicines containing St John's Wort (*Hypericum perforatum*)
- phenytoin or carbamazepine, medicines used to treat epilepsy
- benzodiazepines, medicines used to treat anxiety and sleeping problems
- lithium, a medicine used to treat psychiatric conditions
- methylene blue (used to treat high levels of methemoglobin in the blood)
- tramadol, a pain killer
- morphine, a medicine for severe pain
- cetirizine, a medicine for allergies
- warfarin, a medicine used to prevent blood clots
- linezolid or erythromycin, both antibiotics
- rifampicin, a medicine used to treat tuberculosis
- medicines used for fungal infections, such as ketoconazole
- medicines used to treat HIV/AIDS
- cimetidine, a medicine used to treat reflux and stomach ulcers
- triptans such as sumatriptan, naratriptan and zolmitriptan, medicines used to treat migraines.
- medicines that may affect the heart's rhythm such as certain antibiotics and some antipsychotics.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins, or supplements you are taking and if these affect Mirtazapine Sandoz

4. How do I use Mirtazapine Sandoz?

How much to take

- The usual starting dose is 15 mg per day. Your doctor may slowly increase this dose depending on how you respond to Mirtazapine Sandoz.
- The effective dose for most people is usually between 30 mg and 45 mg per day.
- **Ask your doctor or pharmacist if you are unsure of the correct dose for you.** They will tell you exactly how much to take. Your doctor may have prescribed a different dose.
- **Follow the instructions they give you.** If you take the wrong dose, Mirtazapine Sandoz may not work as well, and your problem may not improve.

When to take Mirtazapine Sandoz

- **Mirtazapine Sandoz should be taken about the same time each day, preferably as a single night-time dose before going to bed.**
Taking it at the same time each day will help you remember when to take it.
- If recommended by your doctor, this medicine may be taken in sub-doses equally divided over the day (for example, once in the morning and once at night-time before going to bed).

How to take Mirtazapine Sandoz

- **Swallow the tablets whole with a full glass of water.**
- If you need to break Mirtazapine Sandoz 30 mg tablets in half, hold the tablet with both hands and snap along the break line.

How long to take Mirtazapine Sandoz

- **Continue taking your medicine for as long as your doctor tells you.**
- For depression, the length of treatment depends on how quickly your symptoms improve.
- Most antidepressants take time to work, so do not be discouraged if you don't feel better right away. Some symptoms may improve in 1 to 2 weeks, but it can take up to 2 to 4 weeks to feel the full benefit of the medicine. It is important to keep taking your medicine even if you feel well, usually for about 4 to 6 months or even longer, to make sure the benefits will last.

If you forget to use Mirtazapine Sandoz

Once daily dosing:

If you forget to take the tablet before you go to bed, do not take the missed dose the next morning. This medicine may cause drowsiness or sleepiness during the day.

Continue treatment in the evening with your usual dose and continue to take it as you would normally.

Twice daily dosing:

- **If you forget your morning dose:** Take your morning dose together with your evening dose.

- **If you forget your evening dose:** Do not take it with the next morning dose. Continue treatment with your usual evening dose and continue to take it as you would normally.
- **If you forget both doses:** Do not try to make up for missed doses. Continue treatment with your usual morning and evening dose the next day.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much Mirtazapine Sandoz

If you think that you have used too much Mirtazapine Sandoz, you may need urgent medical attention.

If you take too many tablets, you may feel drowsy, dizzy, confused, agitated, have increased heart rate, or lose consciousness.

You may also have changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as *Torsade de Pointes*.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Mirtazapine Sandoz?

Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Mirtazapine Sandoz.**
- **Tell your doctor if you have not taken your medicine exactly as prescribed.** Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.
- **Tell your doctor if you feel the tablets are not helping your condition.**
- **Keep all of your doctor's appointments so that your progress can be checked.** Your doctor may do some blood tests from time to time. This helps to prevent unwanted side effects.

Call your doctor straight away if:

- **you develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections.** In rare cases, mirtazapine can cause a shortage of white blood cells (bone marrow depression), resulting in lowering body resistance to infection because Mirtazapine can cause a temporary shortage of white blood cells (granulocytopenia).

In rare cases, Mirtazapine can also cause a shortage of red and white blood cells, as well as blood platelets (aplastic anemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia) These symptoms may appear after 2-6 weeks of treatment.

- **you have any suicidal thoughts or other mental/mood changes.** Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. Until the full effects of your medicine become apparent, these symptoms may increase in the first few weeks of treatment. Information from clinical trials have shown an increased risk of suicidal behaviour in young adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.
- **you or someone you know is showing signs of suicide-related behaviour while taking Mirtazapine Sandoz. These signs include:**

- thoughts or talk about death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability, or agitation.

Any mention of self-harm, violence or suicide must be taken seriously. You may find it helpful to tell a relative or close friend that you are depressed and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Remind any doctor, dentist, or pharmacist you visit that you are using Mirtazapine Sandoz.

Things you should not do

- **Do not take Mirtazapine Sandoz to treat any other complaints unless your doctor tells you to.**
- **Do not give your medicine to anyone else, even if they have the same condition as you.**
- **Do not stop taking your medicine or lower the dosage without checking with your doctor.**
- **Do not let yourself run out of medicine over the weekend or on holidays.**
- **Do not stop taking this medicine, even if you feel better, unless advised by your doctor.** Suddenly stopping this medicine may cause nausea, headache, dizziness, anxiety, agitation. Your doctor may want you to gradually reduce the amount you are taking before stopping completely. This may help reduce the possibility of withdrawal symptoms such as nausea, headache, dizziness, anxiety, and agitation.

Driving or using machines

Do not drive or operate machinery until you know how Mirtazapine Sandoz affects you.

This medicine may cause drowsiness, dizziness or sleepiness in some people and affect alertness and concentration. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Combining this medicine and alcohol can make you more sleepy and less alert. Your doctor may suggest you avoid alcohol while being treated with this medicine.

Looking after your medicine

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Store it in a cool dry place below 25°C away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date, packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General Disorders: • lethargy, drowsiness, or sleepiness • headache • tiredness • swollen ankles or feet due to fluid accumulation (oedema) Gut or Gastrointestinal related: • diarrhoea • constipation • increase in appetite and weight gain • nausea, vomiting • dry mouth Blood pressure related: • dizziness or faintness, especially when getting up quickly from a lying or sitting position (low blood pressure)	Speak to your doctor if you have any of these less serious side effects and they worry you. They are generally mild and do not cause patients to stop taking Mirtazapine Sandoz.

Allergy related:

- abnormal sensations in the mouth sensations of numbness in the mouth or swelling in the mouth
- rash or skin eruption

Joints or muscles related:

- painful joints
- back pain, muscle aches and pains
- restless legs

Skin related:

- abnormal sensation in the skin for example burning, stinging, tickling, or tingling

Hormonal related:

- increased prolactin hormone levels in blood (hyperprolactinemia, including symptoms such as enlarged breasts and/or milky nipple discharge)

Mood or Psychiatric related:

- nightmares/vivid dreams
 - sleepwalking
 - memory problems
 - anxiety
 - insomnia*
 - aggression*
 - urge to move
- *may be symptoms of depression

Others:

- speech disorder
- difficulty in passing urine (urinary retention)
- prolonged painful erection of the penis
- tingling fingers or toes

Serious side effects

Serious side effects	What to do
Mood or Psychiatric related: • suicidal ideation or behaviour • epileptic attack (seizures) • shaking or tremors • attack of excessive excitability (mania) • agitation • confusion • hallucinations • fainting	Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Muscle related: • sudden muscle contractions (myoclonus) • muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis) Heart related: • changes to your heart rhythm Liver related: • yellow colouring of eyes or skin; this may suggest disturbance in liver function Pancreas related: • abdominal pain and nausea; this may suggest inflammation of the pancreas Allergy related: • skin rashes, itching or hives; swelling of the face, lips, or tongue which may cause difficulty breathing • severe skin reactions Infection related: • signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers • fever, sore throat, mouth ulcers, gastrointestinal (stomach, bowels), disturbances and other signs of infection Serotonin syndrome: • a combination of symptoms such as fever, sweating, increased heart rate, uncontrollable diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness Others: • generalised fluid retention with weight gain	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Mirtazapine Sandoz contains

Active ingredient (main ingredient)	mirtazapine
Other ingredients (inactive ingredients)	• maize starch • hypolose • colloidal anhydrous silica • magnesium stearate • hypromellose • titanium dioxide • macrogol 8000 • quinolone yellow aluminium lake (15 mg only) • sunset yellow FCF aluminium lake (15 mg only) • iron oxide red (30 mg only) • iron oxide yellow (15 mg and 30 mg only) • iron oxide black (30 mg only).
Potential allergens	• sugars as lactose This medicine does not contain sucrose, gluten, tartrazine, or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Mirtazapine Sandoz looks like

Mirtazapine Sandoz 15 mg - yellow, film-coated tablets, round, biconvex, one sided score notch (Aust R 117131).

Mirtazapine Sandoz 30 mg - beige, film-coated tablets, round, biconvex with a score notch on one side (Aust R 117156).

Mirtazapine Sandoz 45 mg - white, film-coated tablets, circular, biconvex (Aust R 117157).

Available in blisters of 30 tablets.

Who distributes Mirtazapine Sandoz

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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