

Mirtazapine Sandoz®

mirtazapine tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Mirtazapine Sandoz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT MIRTAZAPINE SANDOZ IS USED FOR

This medicine 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.

This medicine corrects this chemical imbalance and may help relieve the symptoms of depression.

Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

This medicine is not addictive.

BEFORE YOU TAKE MIRTAZAPINE SANDOZ

When you must not take it

Do not take this medicine:

- **if you are allergic to medicines containing mirtazapine**
- **if you are allergic to any of the ingredients listed at the end of this leaflet**

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.

Do not take this medicine if 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.

Ask your doctor or pharmacist if you are not sure if you are or if you have been taking a MAOI medicine.

Do not take this medicine if the packaging is torn or shows signs of tampering.

Do not take this medicine if the expiry date printed on the pack has passed.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Do not give this medicine to a child or adolescent.

The safety of this medicine is patients under 18 years has not been established.

Tell your doctor if:

- **you are allergic to any other medicines, foods, dyes, or preservatives**
- **you are pregnant or plan to become pregnant.**

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.

- **you are breastfeeding or wish to breastfeed.**

It is not known whether this

medicine passes into breast milk.

- **if you have or have had any medical conditions, especially the following:**
 - 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.

If you have not told your doctor about any of the above, tell him/her before you start taking Mirtazapine Sandoz.

Tell your doctor if you react badly to lactose or milk before you start taking Mirtazapine Sandoz.

Mirtazapine Sandoz tablets contain lactose.

Taking other medicines

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

Some medicines may be affected by Mirtazapine Sandoz or may affect how well it works. These include:

- other medicines (eg 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.

Your doctor will tell you what to do if you are taking any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

HOW TO TAKE MIRTAZAPINE SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

How much to take

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly 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.

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.

How to take it

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.

When to take Mirtazapine Sandoz

Take your medicine at 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 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 take it

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Mirtazapine Sandoz. Do this even if there are no signs of discomfort or poisoning.

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.

WHILE YOU ARE TAKING MIRTAZAPINE SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Mirtazapine Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Do not stop taking your tablets until you have spoken to your doctor.

If you develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections, tell your doctor immediately.

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.

If you have any suicidal thoughts or other mental/mood changes, tell your doctor immediately or go to the nearest hospital for treatment.

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.

If you or someone you know is showing signs of suicide-related behaviour while taking Mirtazapine Sandoz, contact your doctor or a mental health professional immediately or go to the nearest hospital for treatment.

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.

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

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

Ask your doctor whether you can breast-feed, while taking Mirtazapine.

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.

Tell your doctor if you feel the tablets are not helping your condition.

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.

Things you must not do

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.

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.

Things to be careful of

Be careful when drinking alcohol while you are taking this medicine.

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.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Mirtazapine Sandoz.

Mirtazapine Sandoz helps most people with depression, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor if you notice any of the following and they bother you:

- lethargy, drowsiness or sleepiness
- headache
- tiredness
- increase in appetite and weight gain
- dry mouth
- nausea, vomiting
- diarrhoea
- constipation
- dizziness or faintness, especially when getting up quickly from a lying or sitting position (low blood pressure)
- swollen ankles or feet due to fluid accumulation (oedema)
- abnormal sensations in the mouth sensations of numbness in the mouth or swelling in the mouth
- aggression
- rash or skin eruption
- nightmares/vivid dreams
- tingling fingers or toes
- painful joints
- back pain, muscle aches and pains
- abnormal sensation in the skin for example burning, stinging, tickling or tingling
- urge to move
- difficulty in passing urine (urinary retention)
- restless legs
- speech disorder
- increased prolactin hormone levels in blood (hyperprolactinaemia, including symptoms such as enlarged breasts and/or milky nipple discharge)
- sleepwalking
- prolonged painful erection of the penis
- memory problems
- anxiety*

- insomnia*

*May be symptoms of depression

Tell your doctor immediately, or go the Accident and Emergency at your nearest hospital if you notice any of the following:

- suicidal ideation or behaviour
- epileptic attack (seizures)
- shaking or tremors
- sudden muscle contractions (myoclonus)
- attack of excessive excitability (mania)
- agitation
- confusion
- hallucinations
- changes to your heart rhythm
- fainting
- yellow colouring of eyes or skin; this may suggest disturbance in liver function
- abdominal pain and nausea; this may suggest inflammation of the pancreas
- generalised fluid retention with weight gain
- skin rashes, itching or hives; swelling of the face, lips, or tongue which may cause difficulty breathing
- severe skin reactions
- 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
- a combination of symptoms such as fever, sweating, increased heart rate, uncontrollable diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness (serotonin syndrome)
- muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis)

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

AFTER TAKING MIRTAZAPINE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store Mirtazapine Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Mirtazapine Sandoz comes in three types of tablets:

Mirtazapine Sandoz 15 mg - yellow, film-coated tablets, round, biconvex, one sided score notch.

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

Mirtazapine Sandoz 45 mg - white, film-coated tablets, circular, biconvex.

Available in blisters of 30 tablets.

Ingredients

Active ingredients:

- Mirtazapine Sandoz 15 mg - 15 mg mirtazapine
- Mirtazapine Sandoz 30 mg - 30 mg mirtazapine
- Mirtazapine Sandoz 45 mg - 45 mg mirtazapine.

Inactive ingredients:

- lactose monohydrate
- maize starch
- hypromellose
- colloidal anhydrous silica
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol 8000.

Mirtazapine Sandoz 15 mg tablets also contain:

- iron oxide yellow
- quinolone yellow aluminium lake
- sunset yellow FCF aluminium lake

Mirtazapine Sandoz 30 mg tablets also contain:

- iron oxide red
- iron oxide yellow
- iron oxide black.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Mirtazapine Sandoz is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road

Macquarie Park, NSW 2113

Australia

Tel: 1800 726 369

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15 mg tablets: AUST R 117131

30 mg tablets: AUST R 117156

45 mg tablets: AUST R 117157