

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 AVANZA?

AVANZA contains the active ingredient mirtazapine. AVANZA is used used in the treatment of depression including relapse prevention.

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

2. What should I know before I use AVANZA?

Do not use if you have ever had an allergic reaction to mirtazapine 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 AVANZA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AVANZA 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 AVANZA?

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

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

5. What should I know while using AVANZA?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using AVANZA.• 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 immediately if you develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections• Tell your doctor if you become pregnant while taking AVANZA, or if you feel the tablets are not helping your condition.
Things you should not do	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how AVANZA affects you.• This medicine may cause drowsiness, dizziness or sleepiness in some people and affect alertness and concentration.
Drinking alcohol	<ul style="list-style-type: none">• You are advised not to drink alcohol while taking AVANZA.
Looking after your medicine	<ul style="list-style-type: none">• Store below 30°C in a dark, dry place.• Keep your tablets in their blister pack until it is time to take them.

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

6. Are there any side effects?

Common side effects include increased appetite and weight gain, lethargy, drowsiness or sleepiness, dizziness, headache, dry mouth, nausea, vomiting, constipation, diarrhoea, back pain, muscle aches and pains, memory problems, nightmares/vivid dreams, anxiety, insomnia, swollen ankles or feet, skin rash. Serious side effects include suicidal ideation and suicidal behaviour, confusion, shaking or tremors, severe skin reactions, and disturbances in the production of blood cells that may cause fever, chills, sore throat or mouth ulcers or other signs of frequent infections.

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.

AVANZA®

Active ingredient(s): *mirtazapine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using AVANZA. **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 AVANZA.**

Where to find information in this leaflet:

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

1. Why am I using AVANZA?

AVANZA contains the active ingredient mirtazapine.

AVANZA is used in the treatment of depression including relapse prevention.

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.

Avanza is not addictive.

2. What should I know before I use AVANZA?

Warnings

Do not use AVANZA if:

- you are allergic to mirtazapine, or 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 trouble breathing.
- Always check the ingredients to make sure you can use this medicine.
- 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 Avanza, do not take MAOI during the next two weeks either.

Taking Avanza with an MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Examples of this type of medicine include phenelzine, tranylcypromine and selegiline.

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

- the packaging is torn or shows signs of tampering..

Check with your doctor if you:

- have or have had any other 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
 - 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 the eye)
 - problems in urinating due to an enlarged prostate
 - unexplainable high fever, sore throat and mouth ulcers
 - galactose intolerance
 - glucose-galactose malabsorption
- take any medicines for any other condition
- are allergic to any other medicines, foods, dyes or preservatives
- react badly to lactose or milk before you start taking AVANZA

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

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether Avanza passes into breast milk.

Use in Children

- Do not give Avanza to a child or adolescent.

- The safety of Avanza 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 AVANZA and affect how it works.

Medicines that may increase the effect of AVANZA include:

- erythromycin, an antibiotic
- medicines used to treat fungal infections such as ketoconazole
- HIV/AIDS medications
- cimetidine, a medicine used to treat reflux and stomach ulcers
- nefazodone, a medicine used to treat depression and anxiety

Medicines that may reduce the effect of AVANZA include:

- phenytoin or carbamazepine, medicines used to treat epilepsy
- rifampicin, a medicine used to treat tuberculosis

Medicines that may increase the risk of side effects if taken with AVANZA include:

- other medicines (eg. SSRIs, venlafaxine, L-tryptophan) for depression, anxiety, obsessive compulsive disorders or pre-menstrual dysphoric disorder
- Monoamine Oxidase Inhibitors (such as tranylcypromine, phenelzine, and selegiline)
- medicines containing St. John's Wort (*hypericum perforatum*)
- benzodiazepines, medicines used to treat anxiety and sleeping problems
- morphine, a medicine for severe pain
- lithium, a medicine used to treat some psychiatric conditions
- methylene blue (used to treat high levels of methemoglobin in the blood)
- tramadol, a pain killer
- linezolid, an antibiotic
- triptans such as sumatriptan, naratriptan and zolmitriptan, medicines used to treat migraine
- cetirizine, a medicine for allergies
- medicines that may affect the heart's rhythm such as certain antibiotics and some anti-psychotics.

Medicines whose effect may be reduced if taken with AVANZA include:

- warfarin, a medicine used to prevent blood clotting

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

4. How do I use AVANZA?

How much to take

- Your doctor will tell you how much Avanza to take each day. Take exactly the amount your doctor tells you.
- The usual starting dose is 15mg per day. Your doctor may slowly increase this dose depending on how you respond to Avanza. The effective dose for most people is usually between 30mg and 45mg per day.
- Your doctor may have prescribed a different dose.
- Keep taking Avanza until your doctor tells you to stop.
- For depression, the length of treatment will depend 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 of your 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.
- Even when you feel well, you will usually have to take Avanza for 4 to 6 months or even longer to make sure the benefits will last.

When to take AVANZA

- Take Avanza at about the same time each day.
- Your doctor will tell you when to take your tablets.
- The tablet(s) should be taken at the same time each day, preferably as a single night-time dose before going to bed; if recommended by your doctor, Avanza may be taken in sub-doses equally divided over the day (once in the morning and once at night-time before going to bed).

How to take AVANZA

- Swallow the tablet(s), without chewing, together with some water or other fluid.

If you forget to take AVANZA

AVANZA should be used regularly at the same time each day.

Once Daily Dosing

If you forget to take the tablet before you go to bed, do not take the missed dose next morning. It may cause drowsiness or sleepiness during the day. Continue treatment in the evening with your normal dose.

Twice Daily Dosing

- Morning dose forgotten - simply take it together with your evening dose.
- Evening dose forgotten - do not take it with the next morning dose. Continue treatment with your normal morning and evening doses.
- Both doses forgotten - do not try to make up for the missed tablets. Continue with your usual morning and evening dose the next day.

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

If you take too much AVANZA

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

If you take too many Avanza tablets, you may feel drowsy, dizzy, confused, and agitated.

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 Torsades 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 AVANZA?

Things you should do

Tell your doctor immediately or go to the nearest hospital for treatment if 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 antidepressant effect of your medicine becomes apparent, it is possible 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 warning signs of suicide-related behaviour while taking Avanza, contact your doctor or a mental health professional right away 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.

All mentions of suicide or violence 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.

Call your doctor straight away if you:

- develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections. Stop taking Avanza and consult with your doctor for a blood test.

In rare cases mirtazapine can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because Avanza can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases Avanza can also cause a shortage of red and white blood cells, as well as blood platelets (aplastic anaemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia). While rare, these symptoms most commonly appear after 4-6 weeks of treatment.

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 Avanza until, or shortly before birth, your baby should be supervised for possible adverse effects.

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

Tell your doctor if for any reason 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.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

You may need to have blood tests from time to time.

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

Things you should not do

- Do not suddenly stop taking Avanza, or lower the dose, without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not stop taking Avanza, even if you feel better, unless advised by your doctor. Suddenly stopping Avanza may cause nausea, headache, dizziness, anxiety, agitation. Your doctor may want to gradually reduce the amount of Avanza you are taking before stopping completely.
- Do not use Avanza to treat any other conditions unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Driving or using machines

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

Avanza may cause drowsiness, dizziness or sleepiness in some people and affect alertness and concentration.

If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

You are advised not to drink any alcohol while taking Avanza.

Combining Avanza 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

- Store below 30°C in a dark, dry place.
- Keep your tablets in their blister pack until it is time to take them.
The tablets may not keep as well if you take them out of the blister pack.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place 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.

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.

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
<p>Metabolism and nutrition-related:</p> <ul style="list-style-type: none"> • increase in appetite and weight gain <p>Muscle/skeleton-related:</p> <ul style="list-style-type: none"> • painful joints • back pain • muscle aches and pains <p>Skin-related:</p> <ul style="list-style-type: none"> • rash or skin eruptions 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<p>Head and nervous system-related:</p> <ul style="list-style-type: none"> • lethargy, drowsiness or sleepiness • headache • tiredness • dizziness • tingling fingers or toes • restless legs • abnormal sensation in the skin for example burning, stinging, tickling or tingling • speech disorders • memory problems <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> • dry mouth • nausea, vomiting • diarrhoea • constipation • abnormal sensations in the mouth sensations of numbness in the mouth or swelling in the mouth <p>Heart and circulation -related:</p> <ul style="list-style-type: none"> • dizziness or faintness when getting up quickly from a lying or sitting position (low blood pressure) • swollen ankles or feet as a result of fluid accumulation (oedema) <p>Mood-related:</p> <ul style="list-style-type: none"> • aggression • nightmares/vivid dreams • urge to move • anxiety, insomnia. These may be symptoms of depression • sleepwalking <p>Kidney-related:</p> <ul style="list-style-type: none"> • difficulty in passing urine (urinary retention) <p>Hormone-related:</p> <ul style="list-style-type: none"> • increased prolactin hormone levels in blood (hyperprolactinaemia, including symptoms such as enlarged breasts and/or milky nipple discharge) <p>Reproductive system or breast-related:</p> <ul style="list-style-type: none"> • prolonged painful erection of the penis 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty breathing <p>Mood-related:</p> <ul style="list-style-type: none"> suicidal ideation or behaviour attack of excessive excitability (mania) agitation confusion hallucinations <p>Head and nervous system-related:</p> <ul style="list-style-type: none"> epileptic attack (seizures) shaking or tremors sudden muscle contractions (myoclonus) a combination of symptoms such as fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes unconsciousness and increased salivation (serotonin syndrome) <p>Heart and circulation -related:</p> <ul style="list-style-type: none"> changes to your heart rhythm <p>General disorders:</p> <ul style="list-style-type: none"> fainting generalised fluid retention with weight gain <p>Skin-related:</p> <ul style="list-style-type: none"> severe skin reactions <p>Liver-related:</p> <ul style="list-style-type: none"> yellow colouring of eyes or skin; this may suggest disturbance in liver function <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> abdominal pain and nausea; this may suggest inflammation of the pancreas <p>Blood-related:</p> <ul style="list-style-type: none"> signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers <p>Muscle/skeleton-related:</p> <p>muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis)</p>	<p>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.</p>

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 AVANZA contains

Active ingredient (main ingredient)	mirtazapine
Other ingredients (inactive ingredients)	lactose monohydrate maize starch hypromellose magnesium stearate colloidal anhydrous silica Hypromellose macrogol 8000 Colouring agents: titanium dioxide iron oxide yellow (CI 77492) iron oxide red (CI 77491).
Potential allergens	lactose

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

What AVANZA looks like

AVANZA 30 mg is a red-brown tablet.

One side of the tablet is marked with "Organon" or "MSD", the other with the code "TZ" and "5" on both sides of the score. The tablets have a single breakline, which means that they can easily be divided in two if necessary. (Aust R 77115).

The medicine is packed in child-resistant blisters.

Who distributes AVANZA

Organon Pharma Pty Ltd
Level 5, 66 King St
Sydney NSW 2000
Australia

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