

APX-MIRTAZAPINE

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 APX-MIRTAZAPINE?

APX-MIRTAZAPINE contains the active ingredient mirtazapine. APX-MIRTAZAPINE is used to treat depression including relapse prevention.

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

2. What should I know before I use APX-MIRTAZAPINE?

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

3. What if I am taking other medicines?

Some medicines may interfere with APX-MIRTAZAPINE 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 APX-MIRTAZAPINE?

- The usual starting dose is 15 mg per day. Your doctor may slowly increase this dose depending on how you respond to APX-MIRTAZAPINE.
- 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 APX-MIRTAZAPINE?](#) in the full CMI.

5. What should I know while using APX-MIRTAZAPINE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APX-MIRTAZAPINE.• 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	<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 using this medicine suddenly or lower the dose without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Do not drive or operate machinery until you know how APX-MIRTAZAPINE affects you.• APX-MIRTAZAPINE may cause dizziness, drowsiness, or sleepiness in some people and affect alertness and concentration in some people.
Drinking alcohol	<ul style="list-style-type: none">• Combining APX-MIRTAZAPINE and alcohol can make you sleepier and less alert.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in their blister pack until it is time to take them.• Store below 30°C in a dark, dry place.

For more information, see Section [5. What should I know while using APX-MIRTAZAPINE?](#) 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.

APX-MIRTAZAPINE

Active ingredient(s): *Mirtazapine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APX-MIRTAZAPINE. **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 APX-MIRTAZAPINE.**

Where to find information in this leaflet:

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

1. Why am I using APX-MIRTAZAPINE?

APX-MIRTAZAPINE medicine contains the active ingredient Mirtazapine. This medicine corrects this chemical imbalance and may help relieve the symptoms of depression.

APX-MIRTAZAPINE is used to treat 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.

2. What should I know before I use APX-MIRTAZAPINE?

Warnings

Do not use APX-MIRTAZAPINE 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 trouble breathing.
- you are taking another medicine for depression called monoamine oxidase inhibitor (MAOI) or have been taking it within the last 14 days. If you stop taking APX-MIRTAZAPINE, do not take MAOI during the next two weeks either.

Taking APX-MIRTAZAPINE with an MAOI may cause serious reactions 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.

Check with your doctor if you:

- have any other medical conditions like:
 - 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 a certain medicine that may affect the heart's rhythm
 - any mental illness (e.g., schizophrenia, maniac depression)
 - diabetes
 - glaucoma (increased pressure in the eye)
 - problems in urinating due to an enlarged prostate
 - unexplainable high fever, sore throat and mouth ulcers
 - glucose-galactose malabsorption
 - galactose intolerance.
- take medicines for any other condition
- react badly to lactose or milk before you start taking APX-MIRTAZAPINE. APX-MIRTAZAPINE 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 them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take APX-MIRTAZAPINE 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 APX-MIRTAZAPINE until, or shortly before birth, your baby should be supervised for possible adverse effects.

Do not take APX-MIRTAZAPINE 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 be affected by APX-MIRTAZAPINE or may affect how well 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 (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 some 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 clotting
- linezolid or erythromycin, both antibiotics
- rifampicin, a medicine used to treat tuberculosis
- medicines used to treat fungal infections such as ketoconazole
- HIV/AIDS medications
- cimetidine, a medicine used to treat reflux and stomach ulcers
- triptans such as sumatriptan, naratriptan and zolmitriptan, medicines used to treat migraine
- medicines that may affect the heart's rhythm such as certain antibiotics and some anti-psychotics.

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

4. How do I use APX-MIRTAZAPINE?

How much to take / use

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

Your doctor may have prescribed a different dose.

If you do not understand the instructions on the box, ask your doctor or pharmacist.

When to take / use APX-MIRTAZAPINE

APX-MIRTAZAPINE should be used at 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, APX-MIRTAZAPINE 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 it

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

How long to take it

- 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 APX-MIRTAZAPINE

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 dosing daily

- 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 use too much APX-MIRTAZAPINE

If you think that you have used too much APX-MIRTAZAPINE, you may need urgent medical attention.

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.

You may need urgent medical attention.

If you take too many APX-MIRTAPINE 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.

5. What should I know while using APX-MIRTAPINE?

Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking APX-MIRTAPINE.**
- **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. Stop taking APX-MIRTAPINE 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 APX-MIRTAPINE can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases APX-MIRTAPINE 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.

- **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.

- **you or someone you know is showing warning signs of suicide-related behavior while taking APX-**

MIRTAPINE, 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 self-harm, 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.

Remind any doctor, dentist, or pharmacist you visit that you are using APX-MIRTAPINE.

Things you should not do

- **Do not stop using this medicine suddenly or lower the dose without first checking with your doctor.** Your doctor may want to gradually reduce the amount of APX-MIRTAPINE you are taking before stopping completely.
- **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.**
- **Do not stop taking APX-MIRTAPINE even if you feel better. unless advised by your doctor.** Suddenly stopping APX-MIRTAPINE may cause nausea, headache, dizziness, anxiety, agitation.
- **Do not let yourself run out of medicine over the weekend or on holidays.**
- **Do not use APX-MIRTAPINE to treat any other condition unless your doctor tells you to do.**

Driving or using machines

Do not drive or operate machinery until you know how APX-MIRTAPINE affects you.

APX-MIRTAPINE may cause dizziness, drowsiness, or sleepiness in some people and affect alertness and concentration in some people. If any of these occur, do not drive, operate machinery or anything that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Combining APX-MIRTAPINE and alcohol can make you sleepier and less alert. Your doctor may suggest you avoid alcohol while being treated with this medicine.

Looking after your medicine

- 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.
- Store below 30°C in a dark, dry place.

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

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters 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.

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 <ul style="list-style-type: none"> lethargy, drowsiness or sleepiness headache tiredness swollen ankles or feet because of fluid accommodation (oedema) Gut or gastrointestinal related <ul style="list-style-type: none"> diarrhoea constipation increase in appetite and weight gain nausea, vomiting dry mouth Blood pressure related <ul style="list-style-type: none"> dizziness or faintness when getting up quickly from a lying or sitting position (low blood pressure) Allergy related <ul style="list-style-type: none"> abnormal sensations in the mouth sensations of numbness in the mouth or swelling in the mouth rash or skin eruptions Joints or muscle related <ul style="list-style-type: none"> painful joints backpain muscle aches and pains restless legs Skin related	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking APX-MIRTAZAPINE.</p>

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

Hormonal related

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

Mood or psychiatric related

- nightmares/vivid dreams
- sleep walking
- memory problems
- anxiety
- insomnia*
- aggression*
- urge to move

*These maybe symptoms of depression

Others

- speech disorders
- 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 <ul style="list-style-type: none"> suicidal ideation or behaviour epileptic attack (seizures) shaking or tremors attack of excessive excitability (mania) agitation confusions hallucinations fainting Muscle related <ul style="list-style-type: none"> sudden muscle contractions (myoclonus) muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis) Heart related <ul style="list-style-type: none"> change to your heart rhythm Liver related <ul style="list-style-type: none"> yellow colouring of eyes or skin; this may suggest disturbance in liver function 	<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>

Pancreas related <ul style="list-style-type: none"> abdominal pain and nausea; this may suggest inflammation of the pancreas Allergy related <ul style="list-style-type: none"> skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty breathing severe skin reactions Infection related <ul style="list-style-type: none"> signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers gastrointestinal (stomach, bowels), disturbances and other signs of infection Serotonin syndrome <ul style="list-style-type: none"> 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 Others <ul style="list-style-type: none"> 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 APX-MIRTAZAPINE contains

Active ingredient (main ingredient)	Mirtazapine
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Other ingredients (inactive ingredients)	Lactose monohydrate Hyprolose Maize starch Colloidal anhydrous silica Magnesium stearate 15 mg tablet: Opadry Complete Film Coating System 20A2052560 Yellow. 30 mg tablet: Opadry Complete Film Coating System 20A56788 Brown. 45 mg tablet: Opadry Complete Film Coating System 20A58806 White.
Potential allergens	Lactose monohydrate

What APX-MIRTAZAPINE looks like

15 mg

Yellow, biconvex capsule shaped film-coated tablets with a score line in between '0' and '8' on one side and 'A' debossed on the other side. AUST R 183398.

30 mg

Reddish brown, biconvex capsule shaped film-coated tablets with a score line in between '0' and '9' on one side and 'A' debossed on the other side. AUST R 183399.

45 mg

White, biconvex capsule shaped film-coated tablets with '10' debossed on one side and 'A' debossed on the other side. AUST R 183400.

*Some of these presentations and pack sizes may not be marketed.

Who distributes APX-MIRTAZAPINE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

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