

APO-Mirtazapine

Contains the active ingredient mirtazapine

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about mirtazapine. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Mirtazapine. It contains the active ingredient mirtazapine.

It is used to treat depression.

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

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

How it works

Depression is longer lasting or more severe than the "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. Mirtazapine corrects this chemical imbalance and may help relieve the symptoms of depression.

There is no evidence that this medicine is addictive.

Use in children

This medicine must not be used in children or adolescents under 18 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if you have or have had any of the following:

- You are intolerant to lactose - This medicine contains lactose.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You have had an allergic reaction to mirtazapine or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Do not take this medicine if you are taking other medicines called Monoamine Oxidase Inhibitors (MAOIs). MAOIs may be used for the treatment of depression (phenelzine, tranlycypromine,

moclobemide), Parkinson's disease (selegiline), infections (linezolid), or diagnosis of certain conditions/ treatment of certain blood disorders (methylene blue).

There may be others MAOIs also so check with your doctor or pharmacist.

Do not take mirtazapine until 14 days after stopping any MAOI, and do not take MAOIs until 14 days after stopping mirtazapine.

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 have been taking a MAOI medicine.

Do not give mirtazapine to a child or adolescent.

The safety and efficacy of this medicine in patients under 18 years has not been established.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

These tablets contain lactose.

2. You have or have had any medical conditions, especially the following:

- thoughts of suicide or self-harm
- epilepsy (fits or convulsions)
- liver problems, such as jaundice
- kidney problems
- heart problems
- low blood pressure
- any mental illness (e.g. schizophrenia, bipolar disorder)
- diabetes
- glaucoma (increased pressure in the eyes)
- difficulties in urination as a result of an enlarged prostate

- unexplained high fever, sore throat and mouth ulcers
 - fructose intolerance
 - glucose-galactose malabsorption
 - low sodium levels in your blood (hyponatraemia).
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breast-feeding or you plan to breast-feed. Do not take this medicine whilst breast-feeding until you and your doctor have discussed the risks and benefits involved.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines, This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with mirtazapine. These include:

- other medicines for depression (e.g. SSRIs, venlafaxine, nefazodone), anxiety, obsessive compulsive disorders or pre-menstrual dysphoric disorder
- MAOIs (such as phenelzine, tranylcypromine, moclobemide, linezolid, methylene blue and selegiline)
- medicines to help you sleep or calm down (e.g. benzodiazepines and other sedatives or tranquillisers)
- medicines containing St. John's Wort (*hypericum perforatum*)
- phenytoin or carbamazepine, medicines used to treat epilepsy
- warfarin, a medicine used to prevent blood clotting
- erythromycin, an antibiotic

- rifampicin, a medicine used to treat tuberculosis
- medicines to treat fungal infections, such as ketoconazole
- HIV/AIDS medicines
- cimetidine, a medicine used to treat reflux or stomach ulcers
- medicines to treat migraine attacks, such as sumatriptan, naratriptan and zolmitriptan
- tramadol, a strong painkiller
- medicines which may cause your body to gain fluid.
- tryptophan, found in some preparations bought in health food shops

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with mirtazapine.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual starting dose is 15 mg per day. Your doctor may slowly increase your dose depending on how you respond to mirtazapine.

The effective dose for most people is usually between 30 mg and 45 mg per day.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

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

When to take it

This medicine should preferably be taken as a single night-time dose before going to bed.

If recommended by your doctor, your dose may be taken in sub-doses equally divided over the day (e.g. once in the morning and once at night-time before going to bed).

Take this medicine at the same time or times each day.

Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

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 1-2 weeks, but it can take up to 2-4 weeks to feel the full benefit of the medicine.

Even when you feel well, you will usually have to take your medicine for 4-6 months, or even longer, to make sure the benefits will last.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

Once-Daily Dosing:

If you forget to take your dose before going to bed, do not take the missed dose the next morning, because it may cause drowsiness or sleepiness during the day. Wait until the next evening before taking your normal dose.

Do not take a double dose to make up for the missed dose.

Twice-Daily Dosing:

If you forget your morning dose, simply take it together with your evening dose.

If you forget your evening dose, do not take it with the next morning dose. Skip the missed dose and continue treatment with your normal morning and evening doses.

If you have forgotten both doses, you should not make up for the missed doses; the next day, just continue with your normal morning and evening doses.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant

Tell your doctor immediately, however do not stop taking your medicine until you have spoken to your doctor.

When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

- you are breast-feeding or are planning to breast-feed
It is not known if mirtazapine passes into breast milk, Your doctor will discuss with you the risks and benefits of taking this medicine whilst breast-feeding.
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell your doctor immediately if you develop fever, chills, sore throat or mouth ulcers or experience other signs of infections.

In rare cases mirtazapine can cause a shortage of white blood cells, resulting in lowering body resistance to infection. These symptoms may appear after 2-6 weeks of treatment.

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

Young adults aged 18 to 24 are at particularly high risk of having this happen to them.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. Until the full antidepressant effect of the medicine becomes apparent, it is possible that these symptoms may increase in the first few weeks of treatment.

If you or someone you know is demonstrating any of the following warning signs of suicide while taking this medicine, contact your doctor or health professional immediately or go to the nearest hospital for treatment:

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

All mention of suicide or violence must be taken seriously.

If you have diabetes take care to monitor your blood sugar levels. Your diabetes medication may need to be adjusted.

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 this medicine is not helping your condition.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine suddenly, or change the dosage,

without first checking with your doctor.

Stopping your medicine suddenly may cause nausea, headache, dizziness, anxiety or agitation.

Your doctor may want to gradually reduce the amount of medicine you are taking before stopping completely.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

This medicine may cause drowsiness, sleepiness or dizziness 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.

Be careful when drinking alcohol while taking mirtazapine.

Taking this medicine with alcohol can make you more sleepy and less alert.

Your doctor may suggest you avoid alcohol while being treated with this medicine.

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking mirtazapine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- drowsiness or sleepiness
- headache
- tiredness, feeling weak

- increase in appetite, weight gain
- dry mouth
- diarrhoea
- occasional dizziness or faintness, especially when you get up quickly from a lying or sitting position
- swollen ankles or feet as a result of fluid accumulation (oedema)
- fluid retention with weight gain
- mild rash
- nightmares / vivid dreams
- tingling fingers or toes
- painful joints
- muscle aches and pains
- restless legs

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- itching or any type of skin rash or blistering, peeling or flaking skin
- low sodium levels (feeling weak, sick, confused, exhausted, with muscle weakness or cramps)
- feeling agitated, anxious# or irritable
- feeling extremely restless and having an overwhelming urge to always be moving
- unable to walk properly
- numbness in the mouth
- unable to sleep or stay asleep#
- unusual changes in behaviour
- shaking or tremors
- generalised fluid retention with weight gain
- fever, sore throat, mouth ulcers, gastrointestinal (stomach, bowels) disturbances
- eye pain (a possible sign of glaucoma or raised pressure in the eye)

may be symptoms of depression.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident

and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- thoughts or actions relating to suicide or self-harm
- severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This may be accompanied by fever and chills, aching muscles and generally feeling unwell.
- chest pain, fast or irregular heartbeat.
- epilepsy or fits (seizures)
- shaking or tremors
- sudden muscle contractions (myoclonus)
- fainting, cough and problems breathing (signs of a blood clot on the lung)
- attack of excessive excitability (mania)
- confusion
- hallucinations (hearing, seeing or feeling things that are not there)
- yellow colouring of eyes or skin; this may suggest problems with your liver
- fever, sweating, increased heart rate, uncontrollable diarrhoea, muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness (serotonin syndrome).

Other side effects not listed above may occur in some patients.

Some side effects may occur with no symptoms, and may only be identified by tests. For example, high blood pressure, high cholesterol or fat levels, changes in levels of white or red blood cells.

Allergic reactions

If you think you are having an allergic reaction to mirtazapine, do not take any more of this medicine

and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Mirtazapine looks like

15 mg tablets

Pale Yellow, oval shaped, scored, film coated tablets, imprinted "APO" on one side and "MI" bisect "15" on the other side.

Blister packs and bottles of 30 tablets.

30 mg tablets

Light pink, oval shaped, scored, film coated tablets, imprinted "APO" on one side and "MI" bisect "30" on the other side.

Blister packs and bottles of 30 tablets.

45 mg tablets

White to off-white, oval shaped, unscored, film coated tablets, imprinted "APO" on one side and "MI-45" on the other side.

Blister packs and bottles of 30 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 15 mg, 30 mg or 45 mg of mirtazapine as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- cellulose microcrystalline
- croscarmellose sodium
- magnesium stearate
- hypromellose
- hydroxypropylcellulose
- macrogol 8000
- titanium dioxide
- iron oxide red CI 77491 (30 mg only)
- iron oxide yellow CI 77492 (15 mg and 30 mg only).

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Mirtazapine 15 mg Tablets

Blister: AUST R 127666

Bottle: AUST R 127662

APO-Mirtazapine 30 mg Tablets

Blister: AUST R 127678

Bottle: AUST R 127677

APO-Mirtazapine 45 mg Tablets

Blister: AUST R 127685

Bottle: AUST R 127684

Sponsor

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