

# APO-MIRTAZAPINE TABLETS

Contains the active ingredient mirtazapine

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about Apo-Mirtazapine. It does not contain all the available information.

It does not take the place of talking to your prescriber or pharmacist.

All medicines have risks and benefits. Your prescriber has weighed the risks of you taking Apo-Mirtazapine against the benefits they expect it will have for you.

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

**Keep this leaflet with your medicine.**

You may need to read it again.

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### What this medicine is used for

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Apo-Mirtazapine 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.

**Ask your prescriber if you have any questions about why mirtazapine has been prescribed for you.**

Your prescriber may have prescribed it for another reason.

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

This medicine is not addictive.

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### Before you take this medicine

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#### *When you must not take it*

**Do not take mirtazapine if you are allergic to:**

- mirtazapine
- other medicines containing mirtazapine
- 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.

**Do not take Apo-Mirtazapine 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 Apo-Mirtazapine, do not take MAOI during the next two weeks either.**

Taking Apo-Mirtazapine 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 prescriber 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 expiry date (EXP) printed on the packaging has passed or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Do not give Apo-Mirtazapine to a child or adolescent.

The safety of Apo-Mirtazapine in patients under 18 years has not been established.

#### *Before you start to take it*

Tell your prescriber if you have allergies to any other medicines, foods, preservatives or dyes.

**Tell your prescriber if you have any other health problems, including:**

- 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

**Tell your prescriber if you are pregnant or plan to become pregnant.**

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

**Tell your prescriber if you are breast-feeding or wish to breastfeed**  
It is not known whether Apo-Mirtazapine passes into breast milk.

**If you have not told your prescriber about any of the above, tell them before you start taking mirtazapine.**

Tell your prescriber if you react badly to lactose or milk before you start taking Apo-Mirtazapine.

Apo-Mirtazapine tablets contain lactose.

**Taking other medicines**

**Tell your prescriber or pharmacist if you are taking any other medicines, including any that you get without a prescription from a**

**pharmacy, supermarket or health food shop.**

Some medicines may interfere with mirtazapine or increase the risk of side effects. These include:

- other medicines (eg. 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.

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

These medicines may be affected by mirtazapine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your prescriber or pharmacist has more information on medicines to be careful with or to avoid while taking mirtazapine.

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**How to take this medicine**

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

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack, ask your prescriber or pharmacist for help.**

*How much to take*

**Your prescriber will tell you how much Apo-Mirtazapine to take each day. Take exactly the amount your prescriber tells you.**

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

Your prescriber may have prescribed a different dose.

**If you do not understand the instructions on the box, ask your prescriber or pharmacist for help.**

*How to take it*

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

*When to take it*

Take this medicine at the same time each day.

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 prescriber, Apo-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 long to take it for***

#### **Keep taking Apo-Mirtazapine until your prescriber 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 - 4 weeks to feel the full benefit of the medicine.

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

If you have questions about how long to take Apo-Mirtazapine, talk to your prescriber or your pharmacist.

### ***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 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.

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### **If you take too much (overdose)**

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**Immediately telephone your prescriber or Poisons Information Centre (telephone in Australia - 13 11 26; in New Zealand - 0800 POISONS or 0800 764 766) for advice if you think that you or anyone else may have taken too much mirtazapine.**

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

If you take too many Apo-Mirtazapine 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 Torsade de Pointes.

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### **While you are taking this medicine**

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#### ***Things you must do***

**Tell your prescriber immediately if you develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections. Stop taking Apo-Mirtazapine and consult with your prescriber 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 Apo-Mirtazapine can cause a temporary shortage of white blood cells (granulocytopenia).

In rare cases Apo-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). While rare, these symptoms most commonly appear after 4-6 weeks of treatment.

**Tell your prescriber 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 Apo-Mirtazapine, contact your prescriber 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.

If you become pregnant while taking Apo-Mirtazapine, tell your prescriber immediately. **Do not stop taking your tablets until you have spoken to your prescriber.**

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

**Ask your prescriber whether you can breast-feed, while taking Apo-Mirtazapine.**

**If you are about to be started on any new medicine, tell your prescriber and pharmacist that you are taking Apo-Mirtazapine.**

**Take Apo-Mirtazapine exactly as your prescriber has prescribed.** If you do not follow your prescriber's instructions, your condition may not improve, or you may have unwanted side effects.

If, for any reason, you have not taken your medicine exactly as prescribed, tell your prescriber. Otherwise your prescriber may think that it was not effective and change your treatment unnecessarily.

**If you feel the medicine is not helping, tell your prescriber.** This will help your prescriber to determine the best treatment for you.

Be sure to keep all of your prescriber's appointments so that your progress can be checked.

Your prescriber may want to take some blood tests from time to time.

This helps to prevent unwanted side effects.

### ***Things you must not do***

**Do not give Apo-Mirtazapine to anyone else, even if they have the same condition as you.**

**Do not suddenly stop taking Apo-Mirtazapine, or lower the dose, without first checking with your prescriber.**

**Do not let yourself run out of medicine over the weekend or on holidays.**

**Do not stop taking Apo-Mirtazapine, even if you feel better, unless advised by your prescriber.**

Suddenly stopping Apo-Mirtazapine may cause nausea, headache, dizziness, anxiety, agitation.

Your prescriber may want to gradually reduce the amount of Apo-Mirtazapine you are taking before stopping completely.

**Do not use Apo-Mirtazapine to treat any other medical complaints unless your prescriber tells you to.**

### ***Things to be careful of***

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

Apo-Mirtazapine 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.

**You are advised not to drink any alcohol while taking Apo-Mirtazapine.**

Combining Apo-Mirtazapine and alcohol can make you sleepier and less alert. Your prescriber may suggest you avoid alcohol while being treated with this medicine.

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## **Side effects**

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

Apo-Mirtazapine helps most people with depression, but it may have unwanted side effects in a few people.

Like other medicines, mirtazapine can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

**Ask your prescriber or pharmacist to answer any questions you may have.**

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

**Tell your prescriber or pharmacist if you notice any of the following and they worry you:**

- lethargy, drowsiness or sleepiness
- headache
- tiredness
- increase in appetite and weight gain
- dry mouth
- nausea, vomiting
- diarrhoea
- constipation
- dizziness
- dizziness or faintness when getting up quickly from a lying or sitting position (low blood pressure)
- abnormal sensations in the mouth sensations of numbness

in the mouth or swelling in the mouth

- aggression
- swollen ankles or feet as a result of fluid accumulation (oedema)
- rash or skin eruptions
- nightmares/vivid dreams
- tingling fingers or toes
- painful joints
- back pain
- muscle aches and pains
- restless legs
- abnormal sensation in the skin for example burning, stinging, tickling or tingling
- urge to move
- speech disorders
- difficulty in passing urine (urinary retention)
- anxiety, insomnia. These may be symptoms of depression

**Tell your prescriber immediately, or go to 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 rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty breathing
- signs of infection such as sudden unexplainable high

fever, sore throat and mouth ulcers

- 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)
- muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis)

Other adverse effects not listed above may also occur in some patients. Tell your prescriber if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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

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## Storage and disposal

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### *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 prescriber tells you to stop taking this medicine, or it has passed its expiry date, ask your pharmacist what to do with any that is left over.**

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## Product description

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### *What it looks like*

Apo-Mirtazapine 15mg tablets: Pale yellow, oval shaped, scored, film coated tablets, imprinted "APO" on one side and "MI" bisect "15" on the other side.

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

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

Available in blister of 30 tablets.

\*Not all presentations may be marketed.

### *Ingredients*

#### **Active Ingredient:**

Each capsule contains either 15 mg, 30 mg or 45 mg of mirtazapine.

They also contain the following inactive ingredients:

- Croscarmellose sodium
- Microcrystalline cellulose
- Lactose monohydrate
- Magnesium stearate
- Hyprolose
- Hypromellose
- Macrogol 8000 NF

- Purified water
- Titanium dioxide USP (E171)
- Ferric Oxide (Yellow Iron Oxide) (E172) – for 15mg and 30mg only
- Ferric Oxide (Red Iron Oxide) (E172) – for 30mg only

This medicine is gluten free but contains lactose.

### **Sponsor**

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This leaflet was last updated in  
February 2020