

# Mirtanza ODT tablets

*Mirtazapine orally dispersible tablets*

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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 Mirtanza ODT.

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

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

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

Keep this leaflet with your medicine.

You may need to read it again.

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### What Mirtanza ODT is used for

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Mirtanza ODT 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.

**Ask your doctor if you have any questions about why it has been prescribed for you.**

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

Mirtanza ODT is not addictive.

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### Before You Take Mirtanza ODT

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*When you must not take it*

**Do not take Mirtanza ODT:**

- **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 or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

**Do not take Mirtanza ODT 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.**

Taking Mirtanza ODT 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.**

**Do not take Mirtanza ODT if the packaging is torn or shows signs of tampering.**

**Do not take Mirtanza ODT if the expiry date printed on the pack has passed.**

**If you are not sure whether you should start taking Mirtanza ODT, talk to your doctor.**

*Before you start to take it*

**Do not give Mirtanza ODT to a child or adolescent.**

The safety of Mirtanza in patients under 18 years has not been established.

**Tell your doctor if:**

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

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

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

It is not known whether Mirtanza ODT passes into breast milk.

- 4. 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
- 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
- fructose intolerance
- glucose-galactose malabsorption
- sucrose-isomaltase insufficiency
- phenylketonuria

**If you have not told your doctor about any of the above, tell them before you take Mirtanza ODT.**

### *Taking other medicines*

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

Some medicines may be affected by Mirtanza 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 (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
- 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 antipsychotics.

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

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Mirtanza ODT.

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

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## How to take Mirtanza ODT

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**Follow all directions given to you by your doctor and pharmacist.**

They may differ from the information contained in this leaflet.

### *How much to take*

**Your doctor will tell you how much Mirtanza ODT 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 MIRTAZAPINE ODT. The

effective dose for most people is usually between 30mg and 45mg 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 for help.

### *When to take it*

**Take Mirtanza 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, Mirtanza 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*

Mirtanza ODT can be taken with or without water.

**Please read the following instructions carefully**

- To prevent crushing the tablet, do not push against the tablet pocket (see fig. 1)
- Each blister contains ten tablet pockets, which are separated by perforations (dotted lines). Bend the strip several times along the dotted lines, and then tear off one tablet pocket (see fig. 2).
- Carefully peel off the lidding foil, starting in the corner indicated by the arrow (see fig. 3).
- Take out the tablet with dry hands and place it on the tongue. The tablet will rapidly disintegrate and can be swallowed with or without water (see fig. 4 & 5).

**Take the tablet immediately after it is removed from the tablet pocket.**

Once removed it cannot be stored.

## How long to take it

Keep taking Mirtanza ODT 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 - 4 weeks to feel the full benefit of the medicine.

Even when you feel well, you will usually have to take Mirtanza ODT for 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 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 (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 you or anyone else may have taken

too much Mirtanza ODT. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many Mirtanza ODT tablets, you may feel drowsy, dizzy, confused, agitated, have increased heart rate or lose consciousness.

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## While you are taking Mirtanza ODT

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### Things you must do

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

In rare cases Mirtanza ODT 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.**

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.

If you or someone you know is showing warning signs of suicide-related behaviour while taking Mirtanza ODT, 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.

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

**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 your appointments with your doctor so that your progress can be checked.**

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

**Before starting any new medicine, tell your doctor or pharmacist that you are taking Mirtanza ODT.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking Mirtanza ODT.**

### Things you must not do

**Do not drive or operate machinery until you know how Mirtanza ODT affects you.**

Mirtanza ODT 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.

**Do not suddenly stop taking Mirtanza ODT, 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 Mirtanza ODT, even if you feel better, unless advised by your doctor.**

Suddenly stopping Mirtanza ODT may cause nausea, headache, dizziness, anxiety, and agitation.

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

**Do not use Mirtanza ODT 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.**

*Things to be careful of*

**Be careful when drinking alcohol while taking Mirtanza ODT.**

Combining Mirtanza ODT and alcohol can make you more sleepy and less alert. Your doctor may suggest you avoid alcohol while being treated with this medicine.

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## Side Effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Mirtanza ODT.**

Mirtanza ODT 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 treatment if you get some of the side effects.

**Ask your doctor or pharmacist any questions you may have.**

**Do not be alarmed by this list of possible 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
- occasional dizziness or faintness, especially when getting up quickly from a lying or sitting position
- 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
- nightmares/vivid dreams
- tingling fingers/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#  
# may be symptoms of depression
- 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

**Tell your doctor immediately or go to Accident and Emergency at the 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
- yellow colouring of eyes or skin; this may suggest disturbance in liver function
- generalised fluid retention with weight gain
- skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty breathing
- fever, sore throat, mouth ulcers, gastrointestinal (stomach, bowels) disturbances and other signs of infection
- fever, sweating, increased heart rate, 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)

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

**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.**

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## After taking Mirtanza ODT

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### Storage

**Keep your tablets in the blister pack until it is time to take them.**

The tablets will not keep if you take them out of their blister.

**Store below 30 degrees Celsius.**

**Do not store Mirtanza ODT or any other medicine in the bathroom or near a sink.**

**Do not leave Mirtanza ODT in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep this medicine where children cannot reach it.**

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

### *Disposal*

**If your doctor tells you to stop taking Mirtanza ODT, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### *What it looks like*

Mirtanza ODT 15, 30 and 45 mg tablets are presented in a blister pack of 30 or 90 tablets\*.

\*not marketed

#### **MIRTANZA ODT 15 mg**

White, round tablets debossed with '36' on one side and 'A' on the other side with an embossed circular edge.

#### **MIRTANZA ODT 30 mg**

White, round tablets debossed with '37' on one side and 'A' on the other side with an embossed circular edge.

#### **MIRTANZA ODT 45 mg**

White, round tablets debossed with '38' on one side and 'A' on the other side with an embossed circular edge.

### *Ingredients*

#### **Active Ingredient:**

Mirtazapine

Contains Aspartame

#### **Other Ingredients:**

- Crospovidone

- Mannitol
- Microcrystalline cellulose
- Aspartame\*
- Colloidal anhydrous silica
- Magnesium stearate
- Strawberry Guarana 586997 AP0551
- (HF82) N&A Peppermint FL SD # 517

Please read this leaflet carefully before you start taking Mirtanza ODT. You may wish to keep it to read again.

AUST Rs

15 mg: Aust R 183404

30 mg<sup>®</sup>: Aust R 183405

45 mg: Aust R 183406

#### **Name and Address of the Sponsor**

**Arrow Pharma Pty Ltd**

**15-17 Chapel St**

**Cremorne**

**VIC 3121**

Australia

Ph: 1800 195 055

#### **Date of Preparation**

May 2020