

# Axit

contains the active ingredient mirtazapine

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## CONSUMER MEDICINE INFORMATION

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### What is in this leaflet

This leaflet answers some common questions about Axit.

It does not contain all 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 Axit against the benefits expected 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 Axit is used for

Axit is used to treat depression and prevent the return of symptoms.

There are many different types of medicines used to treat depression. Depression is longer lasting and/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 imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being 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.

Axit corrects this chemical imbalance and may help relieve the symptoms of depression.

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

Your doctor may have prescribed Axit for another reason.

**Do not give Axit to children and adolescents younger than 18 years.**

The safety and effectiveness of Axit has not been established in this age group.

Axit is available only with a doctor's prescription.

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### Before you take Axit

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

**Do not take Axit if you are allergic to any other medicines containing mirtazapine (Avanza, Mirtazon, Remeron) 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 or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

**Do not take Axit if you are taking another medicine called a monoamine oxidase inhibitor (MAOI) or have been taking one within the last 14 days.**

Taking Axit 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 are taking, or have been taking a MAOI medicine.**

MAOIs are medicines used to treat depression and Parkinson's disease. Examples of MAOIs are phenelzine (Nardil), tranylcypromine (Parnate) and selegiline (Selgene, Eldepryl).

**Do not take Axit if you have galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, as this medicine contains lactose.**

**Do not take Axit if you are pregnant.**

Axit may affect your developing baby if you take it during pregnancy. Women capable of having children should use proven methods of contraception such as the birth control pill.

**Do not take Axit if you are breastfeeding.**

It is still not known how Axit may affect your baby.

**Do not take Axit if the expiry date (EXP) printed on the pack has passed.**

If you take this medicine after the expiry date, it may not work as well.

**Do not take Axit if the packaging shows signs of tampering or the tablets do not look quite right.**

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

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

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you have or have had any medical conditions, especially the following:**

- thoughts of suicide or self harm
- epilepsy (seizures)
- liver disease such as jaundice
- kidney disease
- heart disease
- low blood pressure
- mental disorders such as schizophrenia and manic depression (alternating periods of elation/overactivity and depressed mood)
- diabetes
- glaucoma (increased pressure in the eye)
- difficulty in urination due to an enlarged prostate
- unexplained high fever, sore throat and mouth ulcers
- fructose intolerance
- glucose-galactose malabsorption.

Your doctor may want to take special care if you have any of these conditions.

**Tell your doctor if you plan to have surgery.**

**If you have not told your doctor about any of the above, tell him/her before you start taking Axit.**

### ***Taking other medicines***

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

Some medicines may be affected by Axit, or may affect how well it works. These include:

- other medicines (eg. SSRIs, venlafaxine) 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
- warfarin, a medicine used to prevent blood clotting.
- erythromycin, an antibiotic
- 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

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

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

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

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## **How to take Axit**

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

They may differ from the information contained in this leaflet.

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

### ***How much to take***

The dose varies from person to person.

The usual starting dose is 15 mg per day. Your doctor may increase this dose depending on how you respond to this medicine. The effective dose

for most people is between 30 and 45 mg daily.

People with kidney or liver problems may require a smaller dose.

### ***How to take it***

**Swallow the tablets with a glass of water.**

**Do not crush or chew the tablets.**

Axit 15 and Axit 30 tablets can be divided in half along the breakline, if advised by your doctor or pharmacist.

### ***When to take it***

Axit can be taken with or without food.

It is preferable to take the tablet at night-time, before going to bed.

If you are advised by the doctor to divide the daily dose, half the daily dose should be taken in the morning and half at night-time before going to bed.

**Take your medicine at about the same time each day.**

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

### ***How long to take it for***

To properly control your condition, Axit must be taken every day strictly as recommended by your doctor.

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so don't be discouraged if you don't feel better right away. Some of your symptoms may improve in 2 to 4 weeks but it can take longer to feel any real improvement. Even when you feel well, you will usually have to take Axit for 4 to 6 months or even longer to make sure the benefits last.

**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.**

**Discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger.**

**After 2 to 4 weeks, visit your doctor to discuss the effect that the treatment has had.**

This will help your doctor to determine the best treatment for you.

**Keep taking Axit for as long as your doctor tells you to.**

### ***If you forget to take it***

#### **DAILY DOSING**

**If you forget to take Axit before you go to bed and you wake up late in the night or early in the morning, do not take Axit as you may have trouble waking in the morning or experience morning drowsiness.**

#### **TWICE DAILY DOSING**

**Morning dose forgotten - simply take it together with your evening dose.**

**Evening dose forgotten - skip the dose you have missed and take your normal morning and evening doses.**

**Both doses forgotten - do not try to make up for the missed doses, continue with your usual morning and evening dose the next day.**

### ***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 Axit. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take too much Axit, you may feel drowsy, sleepy, confused and agitated; have tremors, a fast heart rate, or lose consciousness.

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## **While you are taking Axit**

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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 Axit 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 Axit, 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.

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

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

**Since Axit is to be taken regularly every day, keep a continuous supply of medicine so you don't run out, especially over weekends or on holidays.**

**If you become pregnant while taking Axit, tell your doctor immediately.**

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

Your doctor may want to take some blood tests and check your heart and blood pressure from time to time. This helps prevent unwanted side effects.

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

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

Axit 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 Axit, or lower the dose, without checking with your doctor.**

Your doctor may want you to gradually reduce the amount of Axit you are taking before stopping completely. If you stop Axit suddenly, you may get unwanted side effects such as dizziness, nausea (feeling sick), headache and feel generally unwell.

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

**Do not use Axit to treat any other conditions unless your doctor tells you to.**

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

## **Things to be careful of**

### **Be careful when drinking alcohol while taking Axit.**

Axit can enhance the effect of alcohol. Therefore the doctor may suggest that you avoid taking alcohol while being treated with Axit.

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## **Side effects**

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

Like all other medicines, Axit may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. Elderly people aged 65 years and over may be more sensitive to the side effects of Axit. You may need medical treatment if you get some of the side effects.

### **Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

### **Tell your doctor if you notice any of the following and they worry you:**

- drowsiness or sleepiness
- headache
- tiredness
- increase in appetite and weight gain
- dry mouth
- diarrhoea
- occasional dizziness or faintness, especially when getting up quickly from a lying or sitting position
- swollen ankles or feet as a result of fluid accumulation (oedema)
- rash
- nightmares/vivid dreams
- tingling fingers or toes
- painful joints

- muscle aches and pains
- restless legs
- anxiety\*
- insomnia\*

\* May be symptoms of depression.

### **Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:**

- 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)

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

### **Tell your doctor if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some patients. Some of these side effects (for example, changes in cholesterol level or blood pressure) can only be found

when your doctor does tests from time to time to check your progress.

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## **After taking Axit**

### **Storage**

#### **Keep Axit 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.

#### **Keep your tablets in a cool dry place where the temperature stays below 30°C.**

#### **Do not store Axit or any other medicine in the bathroom or near a sink.**

#### **Do not leave Axit in the car or on window sills.**

Heat and dampness will destroy the medicines.

### **Disposal**

#### **If your doctor tells you to stop taking Axit, 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**

### **What it looks like**

Axit 15 tablets are round, yellow, film-coated tablets marked "MR|15" on one side and "G" on the other.

Axit 30 tablets are round, buff coloured, film-coated tablets marked "MR|30" on one side and "G" on the other.

Axit 45 tablets are round, white, film-coated tablets marked with "MR 45" on one side and "G" on the other.

The tablets for the 15 mg and 30 mg strengths have a breakline and can be broken into two halves if required.

Axit 15, Axit 30 and Axit 45 are available in blister packs of 30 tablets.

## **Ingredients**

The active ingredient in Axit is mirtazapine. Each Axit tablet contains either 15 mg, 30 mg or 45 mg of mirtazapine.

The tablets also contain the following inactive ingredients:

- lactose
- maize starch
- colloidal anhydrous silica
- hydroxypropylcellulose
- magnesium stearate
- Opadry Buff OY-LS-37200 (contains iron oxide yellow CI77492 [E172], iron oxide red CI77491 [E172], iron oxide black CI77499 [E172], in 30 mg tablets only)
- Opadry II complete film coating system 39F52901 Yellow (contains quinoline yellow CI47005 and iron oxide yellow CI77492, in 15 mg tablets only)
- Opadry White OY-LS-28908 (in 45 mg tablets only).

The tablets are gluten free.

## **Manufacturer**

Axit is made in Australia by:

### **Alphapharm Pty Limited**

(ABN 93 002 359 739)

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

[www.alphapharm.com.au](http://www.alphapharm.com.au)

## **Medical Information**

Phone: 1800 028 365

Australian registration number:

Axit 15 - AUST R 97194 (blister pack)

Axit 30 - AUST R 97195 (blister pack)

Axit 45 - AUST R 164493 (blister pack)

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