

AMIRA

(Moclobemide)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AMIRA.

It does not contain all the available information.

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

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What is AMIRA

The name of your medicine is AMIRA.

AMIRA belongs to a group of medicines called antidepressants.

It contains the active ingredient called moclobemide.

AMIRA is available in two strengths: 150 mg and 300 mg tablets.

What AMIRA is used for

Antidepressants are used to treat depression and work on the central nervous system. They are thought to work by their action on brain

chemicals called amines, which are involved in controlling mood.

There are many different types of medicines used to treat depression. AMIRA belongs to a group of medicines called reversible inhibitors of monoamine oxidase (ARIMA).

Your doctor, however, may have prescribed AMIRA for another purpose.

Ask your doctor if you have any questions why AMIRA has been prescribed for you.

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

Before you take AMIRA

Do not take AMIRA if:

- * You have ever had an allergic reaction to AMIRA or any of the ingredients listed at the end of this leaflet
- * You are suffering from severe confusion
- * You are taking clomipramine (Anafranil) or selegiline (Eldepryl)

Taking AMIRA with these medicines may cause a serious reaction called serotonin syndrome. This can cause a sudden increase in body temperature, increase in blood pressure and convulsions.

Do not take AMIRA after the expiry date (EXP) printed on the pack.

It may have no effect at all or, worse, an entirely unexpected effect if you take it after the expiry date.

Do not take AMIRA if the packaging is torn or shows signs of tampering or if the tablets appear damaged in some way.

If you are not sure if you should be taking AMIRA, talk to your doctor.

You must tell your doctor if:

1. You are allergic to any other medicines, foods, dyes or preservatives
2. You have any other health problems including:
 - * liver disease
 - * high blood pressure
 - * kidney problems
 - * thyrotoxicosis, a condition of excessive thyroid hormones
 - * mental illness other than depression
 - * phaeochromocytoma, a rare tumour of the adrenal gland
3. you are pregnant or intend to become pregnant
4. you are breastfeeding or wish to breastfeed

Your doctor will discuss the risks and benefits of using AMIRA when pregnant and while breastfeeding.

Use in children and adolescents (younger than 18 years)

AMIRA is not recommended for use in children and adolescents less than 18 years of age. The safety and efficacy of AMIRA in this age group has not been established.

Taking other medicines

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop.

Some commonly used medicines that may interfere with AMIRA are:

- * cimetidine (Tagamet), a medicine used to treat stomach ulcers or reflux
- * dextromethorphan, cough suppressant, usually in some cough and cold medicines
- * pethidine, a strong pain killer
- * medicines used to relieve migraine (sumatriptan, rizatriptan, naratriptan, zolmitriptan)
- * buspirone, a medicine to treat anxiety disorders

Other antidepressant medicines may interfere with AMIRA such as:

- * fluoxetine (Prozac)
- * paroxetine (Aropax)
- * sertraline (Zoloft)
- * amitriptyline (Tryptanol)
- * nortriptyline (Allegron)

Moclobemide may cause an additional drop in blood pressure if you are taking metoprolol (e.g. Betaloc and Minax)

Your doctor or pharmacist has a complete list of medicines to avoid while taking AMIRA.

If you have not told your doctor about any of the above, tell them before you start taking AMIRA.

How to take AMIRA

Use AMIRA exactly as your doctor has prescribed.

How much to take

Your doctor will tell you how many AMIRA tablets to take each day.

How to take it

Tablets should be swallowed whole with a glass of water.

It may be possible to change from other antidepressants to AMIRA by ceasing the other antidepressant one day and starting AMIRA the next, however you should follow your doctor's instructions carefully and report any unexpected effects if they occur.

When to take it

AMIRA should be taken morning and evening at the end of your meal.

How long to take AMIRA

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 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take AMIRA for several months or even longer to make sure the benefits will last. Continue taking it until your doctor tells you to stop.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember then go back to taking it as soon as you would normally.

Do not double a dose to make up for one you have missed.

In case of an overdose

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have too

much AMIRA, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

Some signs and symptoms of overdose include convulsions, nausea, vomiting, drowsiness, slurred speech, reduced reflexes and agitation.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking AMIRA

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking AMIRA.

Do not take any other medicines, whether they require a prescription or not, without first telling your doctor.

Tell your doctor if you become pregnant while taking AMIRA.

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.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel. This will help your doctor to determine the best treatment for you.

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

Amira is not recommended for use in children and adolescents under 18 years. However, parents and caregivers of children and

adolescents being treated with any antidepressants for major depressive disorder or for any other condition (psychiatric or non-psychiatric) should closely monitor them for any symptoms of agitation, irritability, unusual changes in behaviour, as well as the emergence of thoughts of suicide, and to report such symptoms immediately to their doctor. It is particularly important that monitoring be undertaken during the first few months of antidepressant treatment or at times of dose increase or decrease.

Watch carefully for signs that your depression or anxiety is getting worse, especially in the first few weeks of treatment. Tell your doctor immediately if you experience any of the following symptoms, especially if they are severe, you have not had these symptoms before or they happen very suddenly.

- * Anxiety or agitation
- * Panic attacks
- * Difficulty sleeping
- * Hostility or impulsiveness
- * Restlessness
- * Overactivity or uninhibited behaviour
- * Thoughts of suicide.

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself. All thoughts or talk about suicide or violence are serious. If you or someone you know is showing the following warning signs, either contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment:

- * Thoughts or talk about death or suicide
- * Thoughts or talk about self-harm or doing harm to others
- * Any recent attempts of self-harm
- * An increase in aggressive behaviour, irritability or agitation.

Things you must not do

Do not stop taking AMIRA 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 give this medicine to anyone else even if his or her symptoms seem similar to yours.

Do not use AMIRA to treat other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how AMIRA affects you.

AMIRA causes dizziness in some people at first.

Although drinking alcohol is unlikely to affect your response to AMIRA, your doctor may suggest avoiding alcohol while you are being treated for depression.

Side Effects

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

AMIRA 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 to answer any questions you may have.

In the first week or two you may experience:

Sleep disturbances, dizziness, nausea and headache.

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

- * dizziness
- * nausea
- * headache
- * disturbed sleep
- * upset stomach
- * dry mouth
- * restlessness
- * blurred vision
- * feeling of fullness
- * skin rash
- * flushing
- * feeling of confusion
- * insomnia
- * anxiety
- * diarrhoea
- * constipation

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Stop taking Amira and contact your doctor or go to the emergency department of your nearest hospital if any of the following happens:

- * allergic reaction including swelling of limbs, face, lips, mouth or throat which may cause difficulty swallowing or breathing.
- * Sudden increase in body temperature, agitation, shivering, severe convulsions
- * Fast heart beat, sweating, muscle spasm, racing thoughts, restlessness
- * (see also Things you must do - warning signs of suicide.)

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

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

After taking AMIRA

Storage

Keep AMIRA where young 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 AMIRA in a cool dry place where it stays below 25 degrees C. Protect from moisture.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep your tablets in the packaging until it is time to take them.

If you take the tablets out of the packaging they may not keep well.

Disposal

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

Product Description

What AMIRA looks like

AMIRA comes in two strengths.

AMIRA 150 mg tablets are a yellow, round, biconvex film coated tablet, scored on one side.

AMIRA 300 mg tablets are a white to yellowish-white, oblong, biconvex film coated tablet, scored on one side.

Ingredients

Active ingredient

Each AMIRA 150 mg tablet contains 150 mg of moclobemide.

Each AMIRA 300 mg tablet contains 300 mg of moclobemide.

Inactive ingredients

AMIRA 150 mg & AMIRA 300 mg tablets contain the following inactive ingredients:

Lactose, sodium starch glycollate, povidone, pregelatinised maize starch, magnesium stearate, hypromellose, microcrystalline cellulose, PEG-8 stearate, propylene glycol and titanium dioxide.

AMIRA 150 mg tablets also contain an additional colouring agent yellow iron oxide.

AMIRA tablets are gluten free.

Both strengths are available in blister packs containing 60 tablets.

The Australian Registration Numbers are:

AMIRA 150 mg tablets (AUST R 126317)

AMIRA 300 mg tablets (AUST R 126318)

SUPPLIER

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