

NEW ZEALAND CONSUMER MEDICINE INFORMATION

AURORIX®

Moclobemide film coated tablets 150 mg & 300 mg



What is in this leaflet

Please read this leaflet carefully before you start taking AURORIX.

This leaflet answers some common questions about AURORIX.

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 AURORIX 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 AURORIX is used for

AURORIX belongs to a group of medicines called antidepressants and is used to treat depression and work on the central nervous system.

It contains the active ingredient moclobemide and is thought to work by its action on brain chemicals called amines, which are involved in controlling mood.

There are many different types of medicines used to treat depression. AURORIX belongs to group called reversible inhibitors of monoamine oxidase A.

Your doctor may have prescribed AURORIX for another reason.

Ask your doctor if you have any questions about why this

medicine has been prescribed for you.

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

Before you take AURORIX

When you must not take it

Do not take AURORIX if you have an allergy to:

- any medicine containing moclobemide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are suffering from severe confusion.

Do not take AURORIX if you are taking these medicines:

- selegiline
- bupropion
- triptans (used to treat migraines)
- pethidine (for pain relief)
- tramadol (for pain relief)
- dextromethorphan (found in many cough and cold medicines)
- linezolid (for the treatment of infections).

Do not give this medicine to a child or adolescent under the age of 18 years.

Safety and effectiveness in this age group has not been established.

Do not take this medicine after the expiry date printed on the pack 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 doctor.

Before you start to take it

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

Tell your doctor if you have or have had any of the following medical conditions:

- liver disease
- high blood pressure
- a personal history or family history of bipolar disorder
- mental illness other than depression, including schizophrenia, agitation and excitation
- thyrotoxicosis (a condition of excessive thyroid hormones)
- pheochromocytoma (a rare tumour of the adrenal gland)
- rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

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

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking AURORIX.

In addition to the medicines that you must not take with AURORIX, there are some other medicines that may interfere with AURORIX. These include:

- buprenorphine
- clomipramine
- cimetidine
- dextropropoxyphene
- proton pump inhibitors (e.g. omeprazole, pantoprazole)
- serotonin agonists (e.g. buspirone)
- St. John's wort (hypericum)
- opiates (e.g. morphine, fentanyl, codeine).

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

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

How to take AURORIX

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

They may differ from the information contained in this leaflet.

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

How much to take

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

The usual dose is between 300 mg and 600 mg of moclobemide per day.

How to take it

Swallow the tablets whole with a full glass of water, after a meal.

When to take it

AURORIX tablets are usually taken 2 or 3 times a day, after a meal, depending on the dose your doctor has prescribed for you.

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

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

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

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.

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, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

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

While you are taking AURORIX

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking AURORIX.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if you feel the tablets are not helping your condition.

If you are being treated for depression, tell your doctor immediately if you feel your condition has worsened or if you are experiencing suicidal thoughts.

Things you must not do

Do not take AURORIX to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

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

This medicine may cause dizziness or visual impairment in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much AURORIX. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, drowsiness, slurred speech, reduced reflexes and agitation.

Side effects

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

This medicine 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 the following:

- sleep disturbances
- dizziness
- nausea
- headache
- dry mouth.

Occasionally, the symptoms of depression may include thoughts of

suicide or self-harm. These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur if you are a young adult i.e. under 25 years of age.

Contact your doctor or a mental health professional right away, or go to Accident and Emergency at your nearest hospital for treatment if you or someone you know is demonstrating any of the following warning signs of suicide while taking AURORIX:

- thoughts or talk of 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
- worsening of depression
- insomnia, nervousness, jitteriness
- mania or hypomania (or onset of early symptoms).
- symptoms of Serotonin Syndrome such as fever, sweating, confusion, agitation, diarrhoea and muscle spasms. Serotonin Syndrome symptoms vary, are not specific and may result from the interaction of Aurorix with other medicines, such as buprenorphine containing products.

All thoughts or talk of suicide or violence must be taken seriously.

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

- insomnia
- disturbed sleep
- restlessness
- dizziness
- nausea
- headache
- anxiety
- agitation
- feeling of confusion
- diarrhoea

- vomiting
- tingling or numbness of the hands or feet
- constipation
- feeling of fullness
- upset stomach
- dry mouth
- blurred vision
- skin rash
- flushing
- light-headedness.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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 AURORIX

Storage

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

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

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

Do not store AURORIX 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 it 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 tells you to stop taking this medicine or the expiry date has passed, ask your

pharmacist what to do with any medicine that is left over.

Product description

What it looks like

AURORIX 150 mg: oval, cylindrical, biconvex, pale yellow film coated tablet with a score line on one side and the imprint "150" on the other side.

AURORIX 300 mg: oval, cylindrical, biconvex, white to yellowish white, film coated tablet with a score line on one side and the imprint "300" on the other side.

Ingredients

Active ingredient:

AURORIX 150 mg contains 150 mg of moclobemide as the active ingredient.

AURORIX 300 mg contains 300 mg of moclobemide as the active ingredient.

Inactive ingredients:

AURORIX also contains:

- Lactose monohydrate
- Maize starch
- Povidone
- Sodium starch glycollate
- Magnesium stearate
- Hypromellose
- Macrogol 6000
- Ethyl cellulose
- Purified talc
- Titanium dioxide (E171)
- Yellow iron oxide (E172) in 150 mg tablets only.

150 mg: Contains sulfites and sugars as lactose.

300 mg: Contains sulfites and lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Viatrix Ltd,
PO Box 11183,
Ellerslie,
Auckland
www.viatrix.co.nz
Telephone 0800 168 169

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Aurorix® is a Viatrix company trade mark.