ATOMERRA capsules

atomoxetine (as hydrochloride)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about ATOMERRA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. The updated leaflet may contain important information about ATOMERRA and its use that you should be aware of.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ATOMERRA against the benefits it may have for you.

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

Keep this leaflet with the medicine.

WHAT ATOMERRA IS USED FOR

ATOMERRA is used to treat Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years and older, adolescents and adults. ADHD is a behavioural disorder that causes lack of focus and/or hyperactivity that is much more frequent or severe than others who are close in age or development.

ATOMERRA works by acting on brain chemicals called amines which are involved in controlling behaviour.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed it for another reason.

Available evidence suggests that ATOMERRA does not have a significant potential for abuse.

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

BEFORE YOU TAKE ATOMERRA

When you must not take it

Do not take ATOMERRA if you have an allergy to:

- any medicine containing atomoxetine hydrochloride (the active ingredient in ATOMERRA)
- 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 ATOMERRA if you have any of the following conditions:

- certain heart diseases such as moderate to severe hypertension, abnormal or dangerously fast heart beat, thickening and hardening of the walls of the arteries due to cholesterol deposits
- an uncontrolled overactive thyroid gland which causes increased appetite, weight loss, intolerance to heat, increased sweating, tremors, and rapid heart rate
- a tumour of the adrenal gland, which sits near the kidney. The symptoms are bouts of anxiety and headaches, palpitations, dizziness, a feeling of weakness, nausea, vomiting, diarrhoea, dilated pupils and blurring vision, stomach pains, and raised blood pressure.

Do not take ATOMERRA if you are taking medicine called a monoamine oxidase inhibitor (MAOI) for the treatment of depression or have been taking a MAOI within the last 14 days.
Check with your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.

If you do take ATOMERRA while you are taking a MAOI, you may experience shaking (tremor), shivering, muscle stiffness, fever, rapid pulse, rapid breathing or confusion.

Do not take ATOMERRA if you have high pressure in the eye (glaucoma), or have a family history of glaucoma.

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:

- high blood pressure
- low blood pressure
- fast heart beat
- heart disease
- conditions affecting blood flow in the brain, such as stroke
- liver disease
- kidney disease
- an overactive thyroid gland
- enlargement or disease of the prostate
- difficulty passing urine
- seizures, fits or convulsions
- any psychiatric disorder, including depression or bipolar disorder.

Tell your doctor if you or your child have or have had

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts at self-harm.

You may wish to see a paediatric psychiatrist for further assessment and supervision of your child.

Tell your doctor if you

- are involved in strenuous exercise or activities
- are using a group of medicines called stimulants
- have a family history of sudden/ cardiac death.

ATOMERRA generally should not be used in children, adolescents or adults with known structural heart abnormalities.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.
Your doctor can discuss with you the risks and benefits involved.

Safety and effectiveness in elderly patients older than 65 years and children younger than 6 years have not been established.

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

Taking other medicines

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

Some medicines may be affected by ATOMERRA or may affect how it works. You may need different amounts of your medicines or you may need to take different medicines.

These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression. You should stop taking MAOIs at least two weeks before starting ATOMERRA
- certain medicines used to treat depression such as fluoxetine, paroxetine, desipramine, imipramine, venlafaxine and mirtazapine
- certain medicines used to treat irregular heart beat such as quinidine
- medicines used to treat low blood pressure or to raise blood pressure (pressor agents)
- medicines containing the decongestants pseudoephedrine or phenylephrine
- asthma reliever medicines such as salbutamol, when taken orally as a syrup or as an injection
- certain medicines taken for anxiety such as diazepam or to treat epilepsy such as phenytoin.

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

HOW TO TAKE ATOMERRA

Carefully follow all directions given to you by your doctor or pharmacist.
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

For children and adolescents up to 70 kg body weight, the usual starting dose is approximately 0.5 mg/kg once a day.

After a minimum of 3 days, if necessary, the dose may be increased to approximately 1.2 mg/kg once daily in the morning or as evenly divided doses in the morning and late afternoon/early evening. After 2 to 4 additional weeks, if necessary, the dose may be increased to a maximum of 1.4 mg/kg once daily or 100 mg.

For children and adolescents greater than 70 kg body weight and adults, the usual starting dose is 40 mg once a day.

After a minimum of 3 days, if necessary, the dose may be increased to approximately 80 mg once daily in the morning or as evenly divided doses in the morning and late afternoon/early evening.

After 2 to 4 additional weeks, the dose may be increased to a maximum of 100 mg.

If therapy is interrupted for more than 1 week, treatment should be started at the lowest recommended dose.

Your doctor will tell you how much ATOMERRA you need to take each day.

Your doctor may increase or decrease your dose depending on your condition and any other illness that you may have.

How to take it

Swallow the capsules whole with a full glass of water.

ATOMERRA can be taken with or without food.

When to take it

ATOMERRA is usually taken one or two times a day (early morning and late afternoon/early evening).

If you find that you are sleepy during the day or have trouble sleeping at night, talk to your doctor about the best time to take your medicine.

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.

It does not matter if you take this medicine before or after food.

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.

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 more than your total daily dose in a 24 hour period.

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.

If you take too much (overdose)

If you think that you or anyone else may have taken too much ATOMERRA, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 for advice, or go to Emergency Department at the nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you have taken too much ATOMERRA, the most common signs are sleepiness, agitation, hyperactivity, unusual behaviour and an upset stomach. In some cases of overdose, seizures have been reported.

WHILE YOU ARE TAKING ATOMERRA

Things you must do

Contact your doctor or a paediatric psychiatrist straight away or go to the nearest hospital for treatment if you notice any sudden change in your child's behaviour, if your child is demonstrating any of the following warning signs, if you notice any of the following or if they seem worse.

Signs to watch for:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling very agitated or restless
- panic attacks
- difficulty sleeping (insomnia)
- new or worse irritability
- acting on dangerous impulses
- an extreme increase in activity and talking
- other unusual changes in behaviour.

Preventing suicidal thoughts or action:

To try and prevent suicidal thoughts or actions in your child, talk with and listen to your child about his or her thoughts and feelings and pay close attention to changes in his or her moods or action, especially if the changes occur suddenly. Other important people in your child's life can help by paying attention as well (e.g. brothers and sisters, teachers, caregivers and other important people). Pay close attention to your child whenever ATOMERRA is started or its dose is changed (see Side Effects).

If you notice an increase in aggression or hostility since taking this medication, you should call your doctor as soon as possible.

Tell your doctor if you experience a seizure, fit or convulsion. If you already suffer from seizures, fits or convulsions, tell your doctor if they seem to increase in frequency.

Tell your doctor if you notice changes in your sexual function while you are taking this medicine.

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
It may affect other medicines used during surgery.

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.
Your doctor may do some tests (blood pressure and heart rate) from time to time while on therapy. After starting ATOMERRA children may have a reduced rate of growth so your doctor may also monitor your height and weight from time to time when on long term therapy.

Things you must not do

Do not take ATOMERRA 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 open your STRATERRA capsules as the content is an eye irritant.
In the event of capsule content coming in contact with the eye, flush the affected eye immediately with water and seek medical advice. Hands and any potentially contaminated surfaces should be washed as soon as possible.

Things to be careful of

Be careful driving or operating machinery until you know how ATOMERRA affects you.
This medicine may cause dizziness, tiredness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.
Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

If your doctor advises you to stop taking ATOMERRA, do not take monoamine oxidase inhibitors (MAOIs) within the first two weeks after stopping ATOMERRA.

SIDE EFFECTS

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

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

Children, adolescents and adults

- constipation
- upset or sore stomach, nausea, vomiting
- diarrhoea
- decreased appetite
- decreased weight
- headache
- dizziness
- constant flu like symptoms such as chills, fever, irritated watery eyes, sore throat
- dilated pupils
- mood swings, irritability
- skin rash, redness, itching
- early morning waking, tiredness, difficulty sleeping
- unusual weakness

- lacking energy, feeling tired

Adults

- dry mouth
- thirst
- difficulty urinating, abnormal, painful and/or frequent urination
- sexual problems
- testicular or genital pain in males
- painful or irregular menstrual periods
- hot flushes
- increased sweating
- tickling, tingling, burning, pricking, or numbness of skin
- feeling jittery, tremors
- agitation
- persistent abnormal taste

Tell your doctor immediately or go to the Emergency Department of your nearest hospital if you notice any of the following in you/your child while taking ATOMERRA:

- fast or irregular heart beat
- fainting
- numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to cold
- seizures, fits or convulsions
- signs of liver injury such as dark urine, yellowing of the skin or eyes, severe cramps of the stomach, or unexplained nausea, fatigue, lethargy, itching or flu¬like symptoms
- episodes of overactivity, elation or irritability
- confusion or hallucinations (seeing or feeling things that are not really there)
- thoughts of suicide or attempts to harm yourself (also see Things You Must Do if you notice this behaviour in children or adolescents)

These are serious side effects, which may require medical attention.

Serious side effects are rare or very rare. Other side effects not listed above may also occur in some people.

Tell your doctor or pharmacist if you notice any other effects.

AFTER TAKING ATOMERRA

Storage

Keep your capsules in the pack until it is time to take them.
If you take the capsules out of the pack they may not keep as well.

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

Do not store ATOMERRA or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill 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

ATOMERRA 5 mg*: Yellow capsule body and yellow cap with “5 mg” printed on the capsule body in black

ATOMERRA 10 mg - white capsule body and white cap with “10 mg” printed on the capsule body in black.

ATOMERRA 18 mg - white capsule body and yellow cap with “18 mg” printed on the capsule body in black.

ATOMERRA 25 mg - white capsule body and blue cap with “25 mg” printed on the capsule body in black.

ATOMERRA 40 mg - blue capsule body and blue cap with “40 mg” printed on the capsule body in black.

ATOMERRA 60 mg - yellow capsule body and light blue cap “60 mg” printed on the capsule body in black.

ATOMERRA 80 mg - white capsule body and brown cap with “80 mg” printed on the capsule body in black.

ATOMERRA 100 mg - Brown capsule body and brown cap with “100 mg” printed on the capsule body in black.

*not marketed

Ingredients

ATOMERRA contains 10, 18, 25, 40, 60, 80 or 100 mg of the active ingredient atomoxetine (as hydrochloride).

The capsule filling also contains:

- pregelatinised maize starch
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate

The capsule body and cap contains:

- gelatin
- titanium dioxide
- one or more of the following:
  - indigo carmine
  - iron oxide yellow
  - iron oxide red
  - iron oxide black
- black printing ink (Opacode monogramming ink S-1-277002 Black, ARTG 107581).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Supplied in Australia by:

Arrow Pharma Pty Ltd
15-17 Chapel St
Cremorne, VIC 3121
www.arrowpharma.com.au

Australian Registration Numbers

ATOMERRA:

5 mg capsules – AUST R 234812

10 mg capsules - AUST R 234799

18 mg capsules - AUST R 234793

25 mg capsules - AUST R 234813

40 mg capsules -AUST R 234814

60 mg capsules -AUST R 234808

80 mg capsules -AUST R 234815

100 mg capsules - AUST R 234811

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