

DR. REDDY'S LABORATORIES (PTY) LTD.
INIR 80
APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

INIR 80

Atomoxetine hydrochloride

Capsule

Sugar free

WARNING: SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS

INIR 80 increased the risk of suicidal ideation in children or adolescents.

Patients started on therapy should be closely monitored.

Read all of this leaflet carefully before you start taking INIR 80

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- INIR 80 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What INIR 80 is and what it is used for
2. What you need to know before you take INIR 80
3. How to take INIR 80
4. Possible side effects
5. How to store INIR 80
6. Contents of the pack and other information

1. What INIR 80 is and what it is used for

The active substance is atomoxetine.

INIR 80 increases the amount of noradrenaline in the brain.

This is a chemical that is produced naturally, and increases attention and decreases impulsiveness and hyperactivity in patients with Attention-Deficit/Hyperactivity Disorder (ADHD).

Children and young people with ADHD find it:

- hard to sit still and
- hard to concentrate.

It is not their fault that they cannot do these things. Many children and young people struggle to do these things.

However, with ADHD this can cause problems with everyday life. Children and young people with ADHD may have difficulty learning and doing homework.

They find it hard to behave well at home, at school or in other places. ADHD does not affect the intelligence of a child or young person.

Adults with ADHD find it:

- difficult to do all the things that children find difficult; however, this may mean they have problems with:
 - work
 - relationships
 - low self esteem
 - education

INIR 80:

- is used treat Attention-Deficit/Hyperactivity Disorder (ADHD) in children 6 years of age or older, adolescents and adults.
- helps with your brain activity. It can help improve your attention, help you concentrate, and make you less impulsive.

INIR 80 may take a few weeks after you start the medicine for your symptoms to fully improve.

2. What you need to know before you take INIR 80

Do not take INIR 80 if you:

- are hypersensitive (allergic) to atomoxetine or any of the ingredients of INIR 80 (see section 6).
- have uncontrolled high blood pressure.
- have or had liver problems.
- took a medicine known as a monoamine oxidase inhibitor (MAOI), for example phenelzine, in the last two weeks. A MAOI is sometimes used for depression and other mental-health problems; taking INIR 80 with a MAOI could cause serious side effects or even be life-threatening.
- have serious problems with your heart which may be affected by an increase in heart rate and or blood pressure.
- have a condition called pheochromocytoma (tumour of your adrenal gland).
- have an eye disease called narrow-angle glaucoma (increased pressure in your eye).

Warnings and precautions

Take special care with INIR 80.

Before treatment with INIR 80, tell your doctor if any of the following applies to you as your dose may need to be adjusted:

- if you have thoughts about killing yourself or trying to kill yourself.
- if you hearing voices or seeing things which are not there.
- if you feel angry and aggressive and if your mood changes often.
- if you feel anxious or over-excited and/or unhappy.
- if you have symptoms suggesting an allergic reaction. These symptoms include swelling of the face, lips, tongue, and throat, as well as diffuse skin rash. Should you experience any of these reactions, you should contact your physician immediately.
- if have heart disease or a past medical history of stroke.
- if you have problems with sudden changes in your blood pressure or heart rate.
- if you have high blood pressure. INIR 80 can increase blood pressure;
- if you have low blood pressure. INIR 80 can cause dizziness or fainting in people with low blood

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pressure.

- if you have problems with your heart or an irregular heartbeat. INIR 80 can increase your heart rate (pulse).
- if you have or had had any problems that affect blood flow (poor circulation) and pale fingers and toes and if you start experiencing any of the following headache, weakness, lack of coordination, loss of feeling or tingling.
- if you suffer from convulsions (fits).
- if your child is not growing or gaining weight.
- if you have or had liver problems.
- if you have problems passing urine.

Other medicines and INIR 80

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

In particular, tell your doctor if you are using any of the following:

- medicines called MAOIs (monoamine oxidase inhibitors) including linezolid.
- medicines such as antidepressants e.g., imipramine, venlafaxine, mirtazapine, fluoxetine and paroxetine.
- medicines used for colds and flu e.g., pseudoephedrine or phenylephrine.
- some medicines that cause INIR 80 to stay in the body for longer than normal (such as quinidine and terbinafine).
- salbutamol (a medicine to treat asthma) when taken by mouth or injected may make you feel as if your heart is racing, but this will not make your asthma worse.
- The medicines below may lead to an increased risk of an abnormal rhythm of the heart when taken with INIR 80:
 - medicines used to control the rhythm of the heart (such as anti-psychotics [chlorpromazine, haloperidol and olanzapine], class IA [quinidine, procainamide, and disopyramide] and class III [amiodarone, bretylium, and sotalol] anti-arrhythmic medicines)

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- medicines which change the concentration of salts in the blood (such as thiazide diuretics or water pills)
- medicines for malaria prevention and treatment (such as mefloquine)
- some antibiotic medicines (such as erythromycin and moxifloxacin)
- strong opioid painkillers (such as methadone)
- mood stabilising medicines (such as lithium)
- medicine for heartburn (such as cisapride)
- medicines that increase blood pressure or are used to control blood pressure (such as epinephrine and norepinephrine).
- some cough and cold remedies which contain medicines that can affect blood pressure (such as pseudoephedrine or phenylephrine). It is important to check with your pharmacist when you get any of these products.
- medicines that are known to increase the risk of seizures (such as tricyclic antidepressants [amitriptyline, imipramine, clomipramine] or SSRIs [selective serotonin re-uptake inhibitors such as fluoxetine, escitalopram, paroxetine], anti-psychotics, phenothiazines or butyrophenone, mefloquine, chloroquine, bupropion or tramadol). Caution is also advised if treatment with benzodiazepine medicines is stopped due to possible withdrawal seizures occurring.
- INIR 80 should be used with caution if you are taking medication to control high blood pressure.
- INIR 80 when taken with methylphenidate, does not increase effects on the heart beyond those seen when methylphenidate is taken alone.
- INIR 80 has no effect on alcohol.
- INIR taken with midazolam, resulted in an increase in the levels of midazolam. No dose adjustment is recommended for medicines metabolised by the liver enzyme CYP3A.

This may not be a complete list of all interactions that may occur. Know the medicines you take. Keep a list of them with you to show your doctor and pharmacist each time you get a new medicine.

If you are to have an operation, tell the doctor about your INIR 80 treatment as it may alter the effects of certain medicines used during operations.

Taking INIR 80 with food and drink

INIR 80 can be taken with or without.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking INIR 80.

The safety of INIR 80 during pregnancy and whilst breastfeeding has not been established.

You should not take INIR 80 if you are pregnant.

You should not take INIR 80 if you are breastfeeding your baby.

Driving and using machines

INIR 80 may make you feel sleepy, dizzy, tired or less alert.

Do not drive or use any tools or machines when taking INIR 80.

Use in children and adolescents

INIR 80 should not be used in children under 6 years of age.

Use in elderly

Use INIR 80 with caution in the elderly; they may be more sensitive to its effects.

3. How to take INIR 80

Your doctor will decide on the most suitable treatment for you including on

- the correct dose
- how often and for how long you should be treated and
- whether you should also receive other medicines with INIR 80 or not.

Your doctor will give you all the necessary information on your treatment plan.

Swallow the capsule whole with plenty of water.

The capsules should not be opened and the contents inside the capsules should not be removed and taken in any other way.

Do not open INIR 80 capsules because the contents of the capsule can irritate the eye. If the contents of the capsules come into contact with the eye, the affected eye should be flushed immediately with water, and

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medical advice obtained. Hands and any other part of the body that may have come into contact with the capsule contents should also be washed as soon as possible.

Taking INIR 80 at the same time each day may help you remember to take it.

Do not give INIR 80 to children under six years old.

If you have problems with your liver and/or kidney your doctor may prescribe a lower dose.

If you have the impression that the effect of INIR 80 is too strong or too weak, tell your doctor or pharmacist.

Do not stop treatment early without discussing this with your doctor.

If you take more INIR 80 than you should

The most commonly reported symptoms accompanying overdoses are gastrointestinal symptoms, sleepiness, dizziness, tremor, and abnormal behaviour.

Immediately telephone your doctor if you think that you or anyone else may have taken too much INIR 80 capsules. Do this even if there are no signs of discomfort or poisoning.

If you forget to take INIR 80 for any reason, discuss this with your doctor as soon as possible. Do not take double the dose to make up for the dose you missed.

If you stop taking INIR 80 there are usually no side effects but your ADHD symptoms may return. You should talk to your doctor first before you stop treatment.

4. Possible side effects

INIR 80 can have side effects.

Not all side effects reported for INIR 80 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INIR 80, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens to you or your child, stop taking INIR 80 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reactions including 'swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue, throat and neck which may cause difficulty in swallowing or breathing', throat tightness.

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- shortness of breath and wheezing.
- rash, hives (raised bumps), blisters or itching.
- allergic reactions, including death, can happen in patients taking INIR 80 even after only one dose.

These are all very serious side-effects. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you or your child notice any of the following:

- thoughts and attempts about suicide or dying.
- hearing voices or seeing things which are not there.
- feeling sad (depression), anxious, agitated or irritable.
- acting aggressive, being angry, or violent.
- problem sleeping.
- dark urine.
- yellow skin or yellow eyes.
- stomach pain which is sore when you press it (tenderness) on the right side just below your ribs.
- a feeling of sickness (nausea) that is unexplained.
- tiredness.
- itching.
- feeling that you are coming down with flu.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

Children and adolescents over 6 years	Adults
Decreased and loss of appetite (not feeling hungry)	Decreased appetite (not feeling hungry)
Mood swings; sudden twitches, movements, or sounds; irritability; mood swings; unable to fall	Mood swings; sudden twitches, movements, or sounds; unable to fall asleep; decreased sex drive;

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asleep; feeling agitated; depressed mood; feeling anxious	sleep disorder; feeling agitated; depressed mood; feeling anxious
Headaches, sleepiness, feeling dizzy	Fainting; feeling dizzy; taste is altered; tingling or numbness in the hands or feet or "pins and needles"; sleepiness; shaking movement of the body; headache
Large pupils (the dark centre of the eye)	
	Feeling or having a very fast heartbeat
	Reddening of the skin, usually of the face (flushing), hot flushes, cold hands and feet
Stomach pain, throwing up, feeling sick, hard stools, indigestion	Dry mouth; feeling sick, throwing up, stomach pain, hard stools, indigestion, gas
Inflammation of the skin, rash, itching	Inflammation of the skin, increased sweating, rash
	Pain or burning when passing urine, frequent daytime urination, difficulty to start urinating, incomplete emptying of bladder
	Painful menstrual periods, ejaculation disorder, erectile dysfunction, inflammation of the prostate, testicular pain
Tiredness, lack of strength or energy; chest pain	Tiredness, lack of strength or energy; chest pain; chills; feeling jittery; feeling thirsty; feeling irritable
Increase in blood pressure and heart rate; decrease in weight.	Increase in blood pressure and heart rate; decrease in weight.

Less frequent side effects

Children and adolescents over 6 years	Adults
Suicide-related events, aggression, hostility,	Suicide-related events, aggression, hostility,

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emotional lability*, psychosis (including hallucinations)*	emotional lability*, psychosis (including hallucinations)*, abnormal orgasms, restlessness
Fainting; shaking movement of the body; a headache that can cause severe throbbing pain or a pulsing sensation, usually on one side of the head, often accompanied by nausea, vomiting, and extreme sensitivity to light and sound (migraine); tingling or numbness in the hands or feet or "pins and needles"; decrease in your normal sensations, such as touch or temperature (hypoesthesia); fits	Fainting; a headache that can cause severe throbbing pain or a pulsing sensation, usually on one side of the head, often accompanied by nausea, vomiting, and extreme sensitivity to light and sound (migraine); decrease in your normal sensations, such as touch or temperature (hypoesthesia); fits
Blurred vision, conjunctivitis; abnormal heart rhythm	Blurred vision
Feeling or having a very fast heartbeat	Heart rhythm abnormal
Poor blood circulation, which makes toes and fingers numb and pale (Raynaud's disease)	Poor blood circulation, which makes toes and fingers numb and pale (Raynaud's disease)
Shortness of breath	Shortness of breath
Liver enzyme changes (detected by blood tests).	Liver enzyme changes (detected by blood tests).
Increased sweating; allergic reactions	Itching, hives, allergic reactions
	Muscle spasms
Problems going to the toilet, such as frequent or hesitant urinating, pain during urinating	Problems going to the toilet, such as frequent or hesitant urinating, pain during urinating, sudden need to urinate
Prolonged and painful erections; groin pain in males	Prolonged and painful erections; groin pain in males; ejaculation failure; menstruation disorders
Feeling weak or having no energy	Feeling cold; chest pain

* See Warnings and precautions

If you notice any side effects not on this leaflet, please inform you doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or health care professional. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of INIR 80.

5. How to store INIR 80

Store at or below 25 °C.

Store protected from light and moisture.

Keep the container tightly closed.

Do not use more than 30 days after first opening.

Keep all medicines out of reach and sight of children.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

Return all unused and expired medicines to your pharmacist.

6. Contents of the pack and other information

What INIR 80 contains

Each capsule contains 80 mg atomoxetine hydrochloride equivalent to 80 mg atomoxetine.

The other ingredients of INIR 80 are dimethicone and pregelatinised starch (starch 1500 partially pregelatinised maize starch).

The capsule shell of INIR 80 consists of: gelatin, iron oxide red, iron oxide yellow, titanium dioxide and sodium lauryl sulfate.

What INIR 80 looks like and contents of the pack

White to off-white powder filled in size '1' hard gelatin capsules with opaque dark brown coloured cap and opaque white coloured body imprinted 'RDY' on cap and '563' on body with black ink.

The capsules are packed in white plastic containers with white plastic caps containing 30 capsules.

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Holder of Certificate of Registration

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For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration: Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Access to the corresponding Professional Information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories (Pty) Ltd. website:

<http://www.drreddys.co.za>