

**DR. REDDY'S LABORATORIES (PTY) LTD.
INIR 10/18/25/40/60
APPROVED PATIENT INFORMATION LEAFLET**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S5

INIR 10, capsule

INIR 18, capsule

INIR 25, capsule

INIR 40, capsule

INIR 60, capsule

Atomoxetine hydrochloride

Sugar free

WARNING:

SUICIDAL IDEATION IN CHILDREN AND ADOLESCENTS

Atomoxetine increased the risk of suicidal ideation in children or adolescents. Patients started on therapy with INIR should be closely monitored.

Read all of this leaflet carefully before you or your child starts taking INIR

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

What is in this leaflet:

1. What INIR is and what it is used for
2. What you need to know before you or your child takes INIR
3. How to take INIR
4. Possible side effects

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5. How to store INIR

6. Contents of the pack and other information

1. What INIR is and what it is used for

INIR belongs to the group of medicines called selective norepinephrine (noradrenaline) re-uptake inhibitors.

INIR increases the amount of noradrenaline in the brain.

Children and young people with attention-deficit hyperactivity disorder (ADHD) find it hard to sit still and to concentrate. They may have difficulties learning and doing homework. They find it hard to behave well at home, at school or in other places.

INIR is used to treat ADHD.

INIR helps to improve your and your child's attention and to concentrate.

INIR is used to treat children 6 years of age or older, adolescents and adults with attention-deficit hyperactivity disorder (ADHD).

2. What you need to know before you take INIR

Do not take, or give your child INIR:

- If you or your child is hypersensitive (allergic) to atomoxetine or to any of the other ingredients of INIR (see section 6).
- If you or your child has uncontrolled high blood pressure or if you or your child has liver problems.
- If you or your child has been on treatment with a medicine, known as a monoamine oxidase inhibitor (MAOI), in the last two weeks.

A MAOI is sometimes used to treat depression and other mental health problems.

Taking INIR with a MAOI could cause serious side effects or even be life-threatening.

You also need to wait two weeks after you stop taking INIR before you start taking a MAOI.

- If your doctor has told you that you or your child has narrow angle glaucoma (increased pressure in your eye).
- If your doctor has told you that you or your child has heart and high blood pressure problems.
- If you or your child has a condition called pheochromocytoma (tumour of your adrenal gland).

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Warnings and precautions

Take special care with INIR:

Tell your doctor before taking INIR or giving INIR to your child if you or your child:

- has possible allergic reactions including severe allergic reactions known as anaphylaxis.
- has thoughts about killing yourself, or trying to kill yourself, and if you feel angry.
- has different moods than usual (mood swings).
- suffer from psychotic symptoms including hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious, mania (feeling elated or over-excited, which causes unusual behaviour) and if you are feeling nervous or anxious.
- feels depressed.
- has liver problems.
- you notice changes in your weight, or your child is not growing or gaining weight as expected.
- has heart problems or an increased heart rate.
- has low or high blood pressure.
- has poor circulation which makes fingers and toes numb and pale (Raynaud's disease).
- has cardiovascular disease or past medical history of stroke.
- has a history of epilepsy or have had seizures for any other reason.
- has problems passing urine.
- you are elderly.
- has aggressive feelings.

Serotonin syndrome

Serotonin syndrome is a potentially life-threatening condition which may occur when taking atomoxetine in combination with some other medicines (see section "Other medicines and INIR"). Signs and symptoms of serotonin syndrome may include a combination of the following: confusion, restlessness, incoordination and rigidity, hallucinations, coma, fast heartbeat, increased body temperature, fast changes in blood pressure, sweating, flushing, tremor, overactive reflexes, nausea, vomiting, and diarrhoea. Contact a doctor or go to your nearest emergency department immediately if you think serotonin syndrome is happening to you.

Treatment with atomoxetine may make you or your child feel aggressive, hostile or violent; or may

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aggravate these symptoms if they were present before treatment. It may also cause you to have unusual changes in behaviour or mood (including physical assault, threatening behaviour and thoughts of harming others). If you or your family and/or friends notice any of these reactions, talk to your doctor or pharmacist right away.

Use in children

Do not give INIR to children under the age of 6 years.

Other medicines and INIR

Always tell your healthcare provider if you or your child is taking any other medicine.

(This includes complementary or traditional medicines).

Tell your doctor or pharmacist if you or your child is taking, have recently taken or might take any other medicines.

INIR and other medicines can affect each other causing side effects.

Tell your doctor if you are taking:

- Salbutamol (a medicine to treat asthma) or other medicines that falls into the class of β -2 agonists.
- Medicines that increase or control blood pressure.
- Do not take INIR with medicines called Monoamine oxidase inhibitors (MAOIs) (medicines used to treat depression and other mental-health problems) including linezolid.

INIR may affect or be affected by other medicines. These include:

Some anti-depressants, opioids such as tramadol, and medicines used to treat migraine called triptans.

These medicines may interact with INIR and can lead to serotonin syndrome, a potentially life-threatening condition. (See section "Warnings and Precautions", Serotonin Syndrome).

If you are using any of these medicines, you may not be able to take INIR, or you may need dosage adjustments, or your doctor may need to monitor you carefully for side effects.

INIR with food and drink

INIR can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or plan to become pregnant or think you may be pregnant or are breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking

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INIR.

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

If you are using INIR you should not breastfeed your baby.

Driving and using machines

Do not drive or operate any tools or machines before you are certain that your performance is not affected by INIR.

3. How to take INIR

Do not share medicines prescribed for you or your child with any other person.

Treatment must be initiated by or under the supervision of a medical practitioner with appropriate knowledge and experience of behavioural disorders (for example, paediatrician or psychiatrist).

Always take INIR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is taken one or two times a day.

The capsules should be swallowed whole.

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

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

Do not change the dose or stop taking INIR without talking with your doctor or pharmacist.

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

If you or your child takes more INIR than you should

If you take more than the prescribed dose, get medical help immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

The most commonly reported symptoms accompanying acute and chronic overdoses were sleepiness/drowsiness (somnolence), feeling anxious/ nervous (agitation), more active than is usual (hyperactivity), abnormal behaviour and stomach pain, constipation, increased gas and feeling sick (gastrointestinal symptoms). Very rarely, serotonin syndrome has also been reported, a potentially life-

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threatening condition. (See section "Warnings and precautions", Serotonin Syndrome).

If you or your child forgets to take INIR

You should take it as soon as possible, but you should not take more than your total daily dose in any 24-hour period. Do not take a double dose to make up for forgotten individual doses.

If you or your child stops taking INIR

Do not stop taking INIR unless your doctor tells you or your child to.

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

4. Possible side effects

INIR can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, tongue, mouth or throat, which may cause difficulty in swallowing or breathing (angioneurotic oedema), throat tightness, rash and hives (pale red, raised, itchy bumps).
- allergic reactions, which may be fatal, can happen in patients taking INIR, even after only one dose.

If you or your child has them, you may have had a serious allergic reaction to INIR.

- dark urine.
- yellow skin or yellow eyes.
- stomach pain which is sore when you press it (tenderness) on the right side just below the ribs.
- a feeling of sickness (nausea) that is unexplained.
- tiredness.
- itching.
- feeling that you are coming down with flu.

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

If you or your child has any of the side effects below, see a doctor straight away:

- feeling or having a very fast heartbeat, abnormal rhythms of the heart.
- thinking about or feeling like killing yourself.
- feeling aggressive.
- feeling unfriendly and angry (hostility).
- mood swings or mood changes.

Tell your doctor if you notice any of the following:

Children over the age of 6 years and adolescents

The following side effects have been frequently reported:

Fever or feeling feverish/chills, cough, sore throat, runny or stuffy nose, muscle or body aches, headaches, tiredness (influenza).

Decrease in appetite, lack or loss of appetite (anorexia).

Irritability, feeling troubled or nervous (agitated), anxious, depressed, twitching/jerking of muscles especially on the face (tics).

Feeling dizzy, sleepy/drowsy (somnolence), headache.

Shortness of breath (dyspnoea).

Stomach pain, constipation, indigestion (dyspepsia), feeling sick (nausea), vomiting.

Inflammation of the skin (dermatitis), rash.

Feeling tired (fatigue), laziness (lethargy), chest pain.

Decrease in weight, increase in heart rate, increase in blood pressure.

Feeling aggressive.

Feeling unfriendly and angry (hostility).

The following side effects have been less frequently reported:

Waking early parts of the morning, involuntary crying or uncontrollable episodes of crying and/or laughing, or other emotional displays (emotional lability), if you see or hear things (hallucinations).

Temporary loss of consciousness caused by a fall/drop in blood pressure (syncope), twitching of muscles

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(tremor), headaches that are moderate to severe which occur often or repeatedly (migraine), tingling or pricking sensation ('pins and needles') (paraesthesia), reduced sense of touch or sensation (hypoesthesia), fits/convulsions (seizure).

Dilation of the pupil (mydriasis); blurred vision.

Rapid, strong, or irregular heartbeat (palpitations), increased heartbeat (sinus tachycardia).

Excessively reduced blood flow in response to cold or emotional stress, causing discolouration of the fingers, toes, and occasionally other areas (Raynaud's phenomenon).

Increased levels of bilirubin in the blood, which is picked up by blood tests, inflammation of the liver (hepatitis), liver failure (acute liver failure).

Itching (pruritus), excessive sweating (hyperhidrosis).

Difficulty to start the urine stream when wanting to urinate (urinary hesitation); inability to completely empty the bladder (urinary retention).

Genital pain in men, painful erections (priapism).

Lack of energy (asthenia).

The frequency of the following side effect is unknown:

Involuntary teeth grinding (bruxism).

Adults

The following side effects have been frequently reported:

Decrease in weight.

Waking early in the morning, decrease in sex drive (libido), problems with sleeping, unable to sleep (insomnia), feeling troubled or nervous (agitated), anxious, depressed.

Feeling dizzy, problems sleeping (insomnia), tingling or pricking sensation "pins and needles" sensation (paraesthesia), sinus headache, headache, if you have a foul, salty or metallic taste sensation in your mouth (dysgeusia), sleepy/drowsy (somnolence), twitching of muscles (tremor).

Hot flushes.

Stomach pain, constipation, dry mouth, indigestion (dyspepsia), excessive gas (flatulence), feeling sick (nausea).

Rash, increased sweating (hyperhidrosis), inflammation of the skin (dermatitis).

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Difficulty in urinating (micturition), difficulty to start the urine stream when wanting to urinate (urinary hesitation), inability to completely empty the bladder (urinary retention), painful or difficult urination (dysuria), abnormally frequent urination (pollakiuria).

Dysmenorrhoea (painful periods), irregular periods, ejaculation problems, inflammation of the prostate, male genital pain.

Tiredness (fatigue), chills, lack of energy (asthenia), laziness (lethargy), feeling nervous (jittery) and irritable, thirsty.

Increase in blood pressure and heart rate.

The following side effects have been less frequently reported:

Twitching/jerking of muscles especially on the face (tics), involuntary crying or uncontrollable episodes of crying and/or laughing, or other emotional displays (emotional lability), feeling restless, if you see or hear things (hallucinations).

Temporary loss of consciousness caused by a fall/drop in blood pressure (syncope), headaches that are moderate to severe which occur often or repeatedly (migraine), reduced sense of touch or sensation (hypoesthesia), fits/convulsions (seizure).

Blurred vision.

Fingers and toes are cold (peripheral coldness), excessively reduced blood flow in response to cold or emotional stress, causing discolouration of the fingers, toes, and occasionally other areas (Raynaud's phenomenon).

Shortness of breath (dyspnoea).

Increased levels of bilirubin in the blood, which is picked up by blood tests, inflammation of the liver (hepatitis), liver failure (acute liver failure).

Itching (pruritus).

Muscle spasms.

Sudden urge to urinate (micturition urgency).

Abnormal orgasm, painful erection (priapism).

Feeling cold, chest pain.

Decrease in weight.

Feeling aggressive.

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Feeling unfriendly and angry (hostility).

If any of these side effects get serious, or if you notice any side effects not mentioned in this leaflet, please inform your 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.

5. How to store INIR

Keep all medicines out of reach and sight of children.

Store at or below 25 °C.

Store in original blister packs.

Keep the blisters in the carton until required for use.

Keep the HDPE containers tightly closed.

Store protected from light and moisture.

Do not use after the expiry date stated on the pack.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

The active substance is atomoxetine hydrochloride.

INIR 10: Each capsule contains atomoxetine hydrochloride equivalent to 10 mg atomoxetine.

INIR 18: Each capsule contains atomoxetine hydrochloride equivalent to 18 mg atomoxetine.

INIR 25: Each capsule contains atomoxetine hydrochloride equivalent to 25 mg atomoxetine.

INIR 40: Each capsule contains atomoxetine hydrochloride equivalent to 40 mg atomoxetine.

INIR 60: Each capsule contains atomoxetine hydrochloride equivalent to 60 mg atomoxetine.

The other ingredients are dimethicone and pregelatinised starch.

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What INIR looks like and contents of the pack

INIR 10: White to off- white powder filled in size '4' Hard gelatine capsules with opaque white coloured cap and opaque white coloured body imprinted "RDY" on cap and "519" on body with black ink.

INIR 18: White to off-white powder filled in size '3' hard gelatine capsules with opaque dark gold coloured cap and opaque white coloured body imprinted 'RDY' on cap and '520' on body with black ink.

INIR 25: White to off-white powder filled in size '3' hard gelatine capsules with opaque dark blue coloured cap and opaque white coloured body imprinted 'RDY' on cap and '528' on body with black ink.

INIR 40: White to off-white powder filled in size '1' hard gelatine capsules with opaque dark blue coloured cap and opaque dark blue coloured body imprinted 'RDY' on cap and '521' on body with black ink.

INIR 60: White to off-white powder filled in size '1' hard gelatine capsules with opaque dark blue coloured cap and opaque dark gold coloured body imprinted 'RDY' on cap and '522' on body with black ink.

HDPE containers: The capsules will be packaged in white plastic containers with white plastic caps containing 30 or 500 capsules.

PVC-PVdC/Alu pack: The capsules are packed in blister strips of clear transparent PVC film coated with PVdC on one side and paper backed aluminium foil with heat seal coating on the other side. The blister strips will be packaged in a cardboard box containing 7, 10, or 14 capsules.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.
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Registration numbers

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INIR 18: 43/1.2/0810

INIR 25: 43/1.2/0811

INIR 40: 43/1.2/0812

INIR 60: 43/1.2/0813

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>