

LURATA

Lurasidone Hydrochloride (40mg, 80mg)

What is in this leaflet NPRa (R1/1)06032024/049

1. What *Lurata* is used for and how *Lurata* works
2. Before you use *Lurata*
3. How to use *Lurata*
4. While you are using it
5. Side effects
6. Storage and Disposal of *Lurata*
7. Product Description
8. Manufacturer and Product Registration Holder
9. Date of revision

What *Lurata* is used for and how *Lurata* works

Lurata contains the active ingredient lurasidone, an atypical antipsychotic used in the treatment of schizophrenia in adults and adolescents (aged 13 to 17 over).

Schizophrenia is characterized by symptoms such as:

- Hearing, seeing, or sensing things that are not there
- Suspiciousness and/or mistaken beliefs
- Incoherent speech and behavior
- Emotional flatness

People may also feel depressed, guilty, anxious or tense.

Lurata reduce the symptoms of schizophrenia by blocking receptors in the brain to which dopamine and serotonin attach, thereby, normalizing the activity of the brain.

Your doctor may have prescribed *Lurata* for another reason. Ask your doctor if you have any questions about why *Lurata* has been prescribed for you.

Before you use *Lurata*

When you must not use it

Do not take *Lurata* if you

- Are allergic to lurasidone or any of the ingredients in *Lurata*
- Taking drugs that significantly affect the way *Lurata* is broken down in your body such as
 - Medications for fungal infections such as itraconazole, ketoconazole (except as a shampoo),

fluconazole, posaconazole or voriconazole

- Medicines for an infection such as clarithromycin or telithromycin
- Medicines for HIV infections such as cobicistat, indinavir, nelfinavir, ritonavir, and saquinavir
- Medicines for chronic hepatitis: boceprevir and telaprevir
- Medicine for depression: nefazodone
- Medicine for tuberculosis: rifampicin
- Medicines for seizures: carbamazepine, phenobarbital and phenytoin
- Diuretics (water pills)

Do not take *Lurata* after the expiry date printed on the pack or the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

Pregnancy and lactation

Do not take *Lurata* if you are pregnant, trying to get pregnant or breast-feeding. If you get pregnant while taking *Lurata*, stop taking it immediately and contact your doctor.

You should not take this medicine during pregnancy unless this has been agreed with your doctor.

The following symptoms may occur in newborn babies of mothers that have used lurasidone in the last trimester (last three months) of their pregnancy

- Have trouble sleeping
- Overly sleepy
- Have muscle stiffness or floppy muscles
- Have trouble feeding
- Breathing problems
- Agitation

If your baby develops any of these symptoms, contact your doctor immediately.

Before you start use it

Before you use *Lurata*, talk to your doctor or pharmacist if you are

- Taking any other medicines
- Pregnant, think you are pregnant, or plan to become pregnant.
- Breastfeeding or plan to breastfeed
- Elderly patient suffering from dementia (loss of memory and other mental abilities)

- Exercise vigorously or work in hot or sunny places
- Have a history of diabetes or high blood sugar
- Have a history of liver or kidney problems
- Have involuntary, irregular muscle movements, especially in the face or tongue
- Have high blood pressure or rapid heartbeats
- Have low blood pressure upon standing up
- Suffer from heart disease or have a family history of heart disease, stroke or “mini” stroke
- Have had problems with the way your heart beats (arrhythmias) or are taking medications that affect how your heart beats
- Have heart problems including “QT prolongation”
- At risk of developing blood clots
- Have or have had breast cancer
- Have pituitary tumors
- Drink alcohol or use drugs
- Have had episodes fainting, blackouts or seizures
- Have or have had low levels of white blood cells

Taking other medicines

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

- Any medicines that also work in the brain
- Medicines that lower blood pressure such as diltiazem or verapamil
- Medicines for Parkinson’s disease and restless leg syndrome
- Medicines used for treating migraines
- Medicines used for treating hay fever and other allergic conditions
- Medications such as cisapride (for treating digestive problems), quinidine (for treating heart conditions), bepridil (for treating chest pain)

Tell your doctor or pharmacist if you take any of these medicines since your doctor may have to change the dose of that medicine during treatment with *Lurata*.

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How to use *Lurata*

How much to use

Your doctor or pharmacist will tell you how many tablets you will need to take each day.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

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

Recommended dosage

Schizophrenia

Adults:

Starting dose: 40 mg per day

Recommended dose: 40 to 160 mg per day

Adolescents (13 to 17 years):

Starting dose: 40 mg per day

Recommended dose: 40 to 80 mg per day

When to use it

Swallow whole with a glass of water. Do not chew the tablets.

Take *Lurata* after full meal for best absorption.

How long to use it

Continue taking *Lurata* for as long as your doctor recommends.

If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.

Do not take a double dose to make up for the missed dose. This may increase the chance of you getting an unwanted side effect.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

You may experience sleepiness, tiredness, abnormal body movements, problems with standing and walking, dizziness from low blood pressure and abnormal heart beats.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor, dentists, and pharmacist who are treating you that you are taking *Lurata* if:

- You are to be started on any new medicines
- Needs to have surgery that needs a general anesthesia
- You become pregnant while taking *Latuda*
- You have signs of frequent infections such as fever, chills, sore throat or mouth ulcers.
- Have high blood sugar
- Have a sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions
- Dizziness on standing up, especially when getting up from a sitting or lying position (orthostatic hypotension) or fainting
- High blood prolactin levels

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Lurata* to anyone else, even if they have the same symptoms or condition as you.

Alcohol should be avoided while taking *Lurata*. This is because alcohol will have an additive negative effect.

Avoid consuming grapefruit, grapefruit juice or products containing grapefruit extract while taking *Lurata*. Grapefruit can affect the way *Lurata* works

Things to be careful of

Driving and using machines

Lurata may make you feel drowsy, dizzy and have vision problems. Do not drive a car or operate machinery until you know how *Lurata* affects you

Low blood pressure

Lurata may cause you to feel faint, lightheaded or dizzy, especially when getting up from a lying or sitting position. This is more likely to happen if you are elderly and also at the start of treatment or when the dose is increased. This will usually go away on its own but if it does not, inform your doctor or pharmacist.

Dehydration and overheating

Do not exercise too much and avoid extreme heat when taking *Lurata*.

Side effects

Like all medicines, *Lurata* can cause side effects, although not everybody gets them.

Tell your doctor or pharmacists as soon as possible if you feel do not well while you are taking *Lurata*.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

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

- Nausea, vomiting
- Diarrhea, abdominal pain
- Restlessness, agitation, anxiety
- Unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, rigid posture, stiffness of the arms and legs, slow movements and a shuffling, unbalanced walk
- Sleepiness, difficulty sleeping
- Indigestion
- Increased saliva
- Back pain
- Dizziness
- Decreased appetite
- Blurred vision
- High blood pressure

If any of the following happen, tell your doctor or pharmacist immediately or go to the accident and emergency at your nearest hospital:

- Sudden sign of allergy such as skin rash, itching or hives, swelling of the

LURATA

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face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing

- Severe spasms in the muscles of the shoulders, neck and upper body
- Temporary paralysis, weakness of muscles or muscle pain
- Uncontrolled movements of the tongues, mouth, cheeks, or jaw which may progress to the arms and legs
- Suicidal thoughts or behavior
- Seizure
- Sudden severe headache, loss of vision, loss of coordination, slurred speech, shortness of breath, chest pain, numbness, heat or swelling in the arms and legs (these symptoms may be associated with a blockage in a blood vessel)

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Lurata

Storage

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

Store below 30°C. Do not store any medicine in the bathroom, or near a sink, or on a windowsill.

Keep out of the reach and sight of children.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These

measures will help to protect the environment.

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Product Description

What it looks like

40 mg: White colored, round shaped biconvex, film coated tablets, debossed with "40" on one side and "ML" on other side.

80 mg: Pale green colored, oval shaped biconvex, film coated tablets, debossed with "80" on one side and "ML" on other side.

Ingredients

Active ingredient

Lurasidone hydrochloride

Inactive ingredients

Core

Lactose monohydrate, Mannitol 60, Pregelatinized Starch, Croscarmellose sodium, Povidone K30, Citric acid anhydrous powder, Magnesium stearate

Tablet coating

40 mg: HPMC 2910/ Hypromellose, Titanium Dioxide, Macrogol / PEG, Carnauba wax

80 mg: HPMC 2910/ Hypromellose, Titanium Dioxide, Macrogol / PEG, Iron Oxide Yellow, FD & C Blue

MAL number(s):

Lurata 40

MAL23106003AZ

Lurata 80

MAL23106004AZ

Manufacturer

MSN Laboratories Pvt Ltd
Formulations Division, Unit-II,
Survey Nos. 1277, 1319 to 1324,
Nandigama (Village & Mandal),
Rangareddy District- 509228,
Telangana, India.

Product Registration Holder

Mansa Healthcare Sdn Bhd
B-05-3A, 3 Two Square,
No 2, Jalan 19/1,
46300 Petaling Jaya, Selangor

Date of revision

01/Mar/2024

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