Package leaflet: Information for the user

Lurasidone 18.5mg film-coated tablets
Lurasidone 37mg film-coated tablets
Lurasidone 74mg film-coated tablets

lurasidone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Lurasidone is and what it is used for

This medicine contains the active substance lurasidone and belongs to a group of medicines called antipsychotics.

It is used to treat symptoms of schizophrenia in adults (aged 18 years and over) and adolescents aged 13-17 years. Lurasidone works by blocking receptors in the brain to which the substances dopamine and serotonin attach. Dopamine and serotonin are neurotransmitters (substances that allow nerve cells to communicate with each other) that are involved in the symptoms of schizophrenia. By blocking their receptors, lurasidone helps to normalise the activity of the brain, reducing the symptoms of schizophrenia.

Schizophrenia is a disorder with symptoms such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech and behaviour and emotional flatness. People with this disorder may also feel depressed, anxious, guilty, or tense. This medicine is used to improve your symptoms of schizophrenia.

2. What you need to know before you take Lurasidone

Do not take Lurasidone
- if you are allergic to lurasidone or any of the other ingredients of this medicine (listed in section 6).
- if you are taking medicines which may affect the level of lurasidone in your blood such as:
  - medicines for fungal infections such as itraconazole, ketoconazole (except as a shampoo), posaconazole or voriconazole
  - medicines for an infection such as the antibiotic clarithromycin or telithromycin
  - medicines for HIV infections such as cobicistat, indinavir, nelfinavir, ritonavir and saquinavir
  - medicines for chronic hepatitis such as boceprevir and telaprevir
  - a medicine for depression, nefazodone
  - a medicine for tuberculosis, rifampicin
  - medicines for seizures such as carbamazepine, phenobarbital and phenytoin
  - herbal medicine for depression, St John's wort (Hypericum perforatum).

Warnings and precautions

It may take several days or even weeks before this medicine will have a full effect. Contact your doctor if you have questions on this medicine.

Talk to your doctor or pharmacist before taking Lurasidone, or during treatment, especially if you have:
- suicidal thoughts or behaviour
- Parkinson's disease or dementia
- ever been diagnosed with a condition whose symptoms include high temperature and muscle stiffness (also known as neuroleptic malignant syndrome) or if you have ever experienced rigidity, tremors or problems moving (extrapyramidal symptoms) or abnormal movements of the tongue or face (tardive dyskinesia). You should be aware that these conditions may be caused by this medicine
- heart disease or heart disease treatment that makes you prone to low blood pressure or have a family history of irregular heartbeat (including QT prolongation)
- a history of seizures (fits) or epilepsy
- a history of blood clots, or if someone else in your family has a history of blood clots, as medicines for schizophrenia have been associated with formation of blood clots
- enlarged breasts in males (gynecomastia), milky nipple discharge (galactorrhea), absence of menstruation (amenorrhea) or erectile dysfunction
- diabetes or are prone to diabetes
- decreased kidney function
- decreased liver function
- an increase in your weight
- blood pressure dropping upon your standing up which may cause fainting
- opioid dependence (treated with buprenorphine) or severe pain (treated with opioids) or depression or other conditions that are treated with antidepressants. The use of these medicines together with Lurasidone can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Lurasidone").

If you have any of these conditions, **please talk to your doctor as he/she may want to adjust your dose, monitor you more closely or stop treatment with Lurasidone**.

Children and adolescents

Do not use this medicine in children and adolescents under 13 years of age.

Other medicines and Lurasidone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking:
- any medicines that also work in the brain, as their effects could be additive in a negative way with the effects of Lurasidone on your brain
- medicines that lower blood pressure, as this medicine can also lower blood pressure
- medicines for Parkinson's disease and restless legs syndrome (e.g. levodopa) as this medicine can reduce their effects
- medicines containing ergot alkaloid derivatives (used for treating migraines), and other medicines including terfenadine and astemizole (used for treating hay fever and other allergic conditions), cisapride (used for treating digestive problems), pimozide (used for treating psychiatric illnesses), quinidine (used for treating heart conditions), bepridil (used for treating chest pain)
- medicines containing buprenorphine (used for treating opioid dependence) or opioids (used for treating severe pain) or anti-depressants such as moclobemide, tranylcypromine, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepin or trimipramine. These medicines may interact with Lurasidone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C.

Contact your doctor when experiencing such symptoms.

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

The following medicines may increase the level of lurasidone in your blood:
- diltiazem (to treat high blood pressure)
- erythromycin (to treat infections)
- fluconazole (to treat fungal infections)
- verapamil (to treat high blood pressure or chest pain).

The following medicines may decrease the level of lurasidone in your blood:
- amprenavir, efavirenz, etravirine (to treat HIV infection)
- aprepitant (to treat nausea and vomiting)
- armodafinil, modafinil (to treat sleepiness)
- bosentan (to treat high blood pressure or ulcers of the fingers)
- nafcillin (to treat infections)
- prednisone (to treat inflammatory disease)
- rufinamide (to treat seizures).

Tell your doctor if you take any of these medicines since your doctor may change your dose of Lurasidone.

Lurasidone with food, drink and alcohol

Alcohol should be avoided when taking this medicine. This is because alcohol will have an additive negative effect.

Do not drink grapefruit juice while you are taking this medicine. Grapefruit can affect the way this medicine works.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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

If your doctor decides that the potential benefit of treatment during pregnancy justifies the potential risk to your unborn baby, your doctor will monitor your baby closely after birth. This is because the following symptoms may occur in newborn babies of mothers that have used lurasidone in the last trimester (last three months) of their pregnancy:
- shaking
- muscle stiffness and/or weakness
- sleepiness
- agitation
- breathing problems
- difficulty in feeding.

If your baby develops any of these symptoms you should contact your doctor.

It is not known if lurasidone passes into breast milk. Talk to your doctor if you are breast-feeding, or if you plan to breast-feed.

Driving and using machines

Sleepiness, dizziness and vision problems may occur during treatment with this medicine (see section 4, Possible side effects). Do not drive, cycle or use any tools or machines until you know that this medicine does not affect you in a negative way.

Lurasidone contains sodium

This medicine contains less than 1mmol sodium (23mg) per one tablet, that is to say essentially 'sodium-free'.

3. How to take Lurasidone

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your dose will be decided by your doctor and may depend on:
- how well you respond to a dose
- if you are taking some other medicines (see section 2, Other medicines and Lurasidone)
- if you have kidney or liver problems.

Adults (aged 18 years and over)

The recommended starting dose is 37mg once a day.

The dose may be increased or decreased by your doctor within the dose range of 18.5mg to 148mg once a day. The maximum dose should not exceed 148mg once a day.

Adolescents aged 13-17 years

The recommended starting dose is 37mg of lurasidone once daily.

The dose may be increased or decreased by your doctor within the dose range of 37mg to 74mg once daily. The maximum daily dose should not exceed 74mg.

How to take Lurasidone

Swallow your tablet(s) whole with water, in order to mask the bitter taste. You should **take your dose regularly every day at the same time of the day**, so that it is easier to remember it. You must take this medicine with food or just after eating, as this helps the body to take up the medicine and allows it to work better.

If you take more Lurasidone than you should

If you take more of this medicine than you should, contact your doctor immediately. You may experience sleepiness, tiredness, abnormal body movements, problems with standing and walking, dizziness from low blood pressure and abnormal heartbeats.

If you forget to take Lurasidone

Do not take a double dose to make up for a forgotten dose. If you miss one dose, take your next dose on the day after the missed dose. If you miss two or more doses, contact your doctor.

If you stop taking Lurasidone tablets

If you stop taking this medicine you will lose the effects of the medicine. You should not stop this medicine unless told to do so by your doctor as your symptoms may return.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following symptoms seek medical attention immediately:
- a severe allergic reaction seen as fever, swollen mouth, face, lip or tongue, shortness of breath, itching, skin rash and sometimes a drop in blood pressure (hypersensitivity). These reactions are seen commonly (may affect up to 1 in 10 people)
- a serious blistering rash affecting the skin, mouth, eyes and genitals (Stevens-Johnson syndrome). This reaction is seen with unknown frequency
- fever, sweating, muscle stiffness and reduced consciousness. These could be symptoms of a condition known as neuroleptic malignant syndrome. These reactions are seen rarely (may affect up to 1 in 1,000 people)
- blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.

The following side effects may also happen in adults:

Very common (may affect more than 1 in 10 people):
- feeling of restlessness and inability to sit still
- nausea (feeling sick)
- insomnia.

Common (may affect up to 1 in 10 people):
- Parkinsonism: this is a medical term that describes many symptoms which include increase in saliva secretion or watery mouth, drooling, jerks when bending the limbs, slow, reduced or impaired body movements, no expression in the face, muscle tightness, stiff neck, muscle stiffness, small shuffling, hurried steps and lack of normal arm movements when walking, persistent blinking in response to tapping of the forehead (an abnormal reflex)
- speech problems, unusual muscle movements; a collection of symptoms known as extrapyramidal symptoms (EPS) which typically will involve unusual purposeless involuntary muscle movements
- fast heartbeat
- increased blood pressure
- dizziness
- muscle spasms and stiffness

- vomiting (being sick)
- diarrhoea
- back pain
- rash and itching
- indigestion
- dry mouth or excess saliva
- abdominal pain
- somnolence, tiredness, agitation and anxiety
- weight gain
- increase in creatine phosphokinase (an enzyme in muscles) seen in blood tests
- increase in creatinine (a marker of kidney function) seen in blood tests
- reduced appetite.

Uncommon (may affect up to 1 in 100 people):
- slurred speech
- nightmares
- difficulty swallowing
- irritation to lining of stomach
- sudden feelings of anxiety
- convulsion (fits)
- chest pain
- muscle aches
- temporary loss of consciousness
- spinning sensation
- abnormal nerve impulses in the heart
- slow heart rate
- joint pains
- problems walking
- rigid posture
- increased blood prolactin, increased blood glucose (blood sugar) and increase in some liver enzymes, seen in blood tests
- blood pressure dropping upon standing up which may cause fainting
- common cold
- hot flush
- blurred vision
- sweating
- pain when passing urine
- uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia)
- low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatremia)
- lack of energy (lethargy)
- gas (flatulence)
- neck pain
- problems with erections
- painful or absence of menstrual periods
- reduced levels of red blood cells (which carry oxygen around the body).

Rare (may affect up to 1 in 1,000 people):
- Rhabdomyolysis which is the breakdown of muscle fibres that leads to the release of muscle fibre contents (myoglobin) into the bloodstream, seen as muscle pain, being sick, being confused, an abnormal heart rate and rhythm, and possibly dark urine
- increase in eosinophils (a type of white blood cell)
- swelling beneath the skin surface (angioedema)
- deliberate injury to oneself
- cerebrovascular accident
- kidney failure
- reduced levels of white blood cells (which fight infection)
- breast pain, milk secretion from breasts
- sudden death.

Not known (frequency cannot be estimated from the available data):
- reduced levels of a subgroup of white blood cells (neutrophils)
- sleep disorder
- newborn babies may show the following: agitation, increase or decreases in muscle tone, tremor, sleepiness, breathing or feeding problems
- abnormal breast enlargement.

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking medicines for schizophrenia compared with those not receiving these medicines.

The following side effects may happen in adolescents:

Very common (may affect more than 1 in 10 people):
- feeling of restlessness and inability to sit still
- headache
- sleepiness
- nausea (feeling sick).

Common (may affect up to 1 in 10 people):
- reduced or increased appetite
- abnormal dreams
- difficulty in sleeping, tension, agitation, anxiety and irritability
- physical weakness, tiredness
- depression
- psychotic disorder: this is a medical term that describes many mental diseases that cause abnormal thinking and perceptions; people with psychoses lose touch with reality
- symptoms of schizophrenia
- difficulty in attention
- spinning sensation
- abnormal involuntary movements (dyskinesia)
- abnormal muscle tone, including torticollis and involuntary upward deviation of the eyes
- Parkinsonism: this is a medical term that describes many symptoms which include increase in saliva secretion or watery mouth, drooling, jerks when bending the limbs, slow, reduced or impaired body movements, no expression in the face, muscle tightness, stiff neck, muscle stiffness, small shuffling, hurried steps and lack of normal arm movements when walking, persistent blinking in response to tapping of the forehead (an abnormal reflex)
- fast heartbeat
- difficulty in emptying the bowels (constipation)
- dry mouth or excess saliva
- vomiting (being sick)
- sweating
- muscle rigidity
- problems with erections
- increase in creatine phosphokinase (an enzyme in muscles) seen in blood tests
- increase in blood prolactin (a hormone) seen in blood tests
- weight gain or loss.

Uncommon (may affect up to 1 in 100 people):
- hypersensitivity
- common cold, infection of throat and nose
- decreased activity of thyroid, inflammation of thyroid
- aggressive behaviour, impulsive behaviour
- apathy
- confusional state
- depressed mood
- separation of normal mental processes (dissociation)
- hallucination (auditory or visual)
- homicidal thoughts
- difficulty in sleeping
- sexual desire increased or decreased
- lack of energy
- mental condition changes
- obsessive thoughts
- feeling of acute and disabling anxiety (panic attack)
- engage in involuntary movements that serve no purpose (psychomotor hyperactivity)
- hyperactivity of the muscles in the body (hyperkinesia), inability to rest (restlessness)
- uncontrollable urge to move legs (restless legs syndrome), uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia)
- sleep disorder
- deliberate suicidal thoughts
- thinking abnormal
- unsteadiness (spinning sensation)
- alteration of taste
- memory impairment
- abnormal skin sensation (paraesthesia)
- feeling of a tight band around head (tension headache), migraine
- difficulty of the eyes in focusing, vision blurred
- increased sensitivity of hearing
- palpitations, alterations in heart rhythm
- blood pressure dropping upon standing up which may cause fainting
- increased blood pressure
- abdominal pain or disturbance
- absence of or deficiency in secretion of saliva
- diarrhoea
- indigestion
- dry lips
- toothache
- partial or complete absence of hair, abnormal hair growth
- rash, urticaria
- muscle spasms and stiffness, muscle aches
- joint pains, pain in arms and legs, pain in jaw
- presence of bilirubin in urine, presence of protein in urine, a marker of kidney function
- pain or difficulty when passing urine, frequent urination, renal disorder
- sexual dysfunction
- difficulty in ejaculation
- abnormal breast enlargement, breast pain, milk secretion from breasts
- menstruation absent or irregular
- make uncontrolled noises and movements (Tourette's disorder)
- chills
- problems walking
- malaise
- chest pain
- fever
- intentional overdose
- effects on the thyroid function, seen in blood tests
- increased blood cholesterol, increased blood triglycerides, decreased high density lipoprotein, decreased low density lipoprotein, seen in blood tests
- increased blood glucose (blood sugar), increased blood insulin, increase in some liver enzymes (a marker of liver function), seen in blood tests
- increased or decreased blood testosterone, increased blood thyroid stimulating hormone, seen in blood tests
- electrocardiogram alterations
- decreased haemoglobin, reduced levels of white blood cells (which fight infection) seen in blood tests.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme (website: www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lurasidone

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and on the carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What this medicine contains
- The active substance is lurasidone.
  Each tablet contains 18.5, 37 or 74mg of lurasidone respectively.
- The other ingredients in the tablets are cellulose, microcrystalline 102 and 101 (E460), mannitol (E421), hypromellose 2910 (E464), croscarmellose sodium (E468), titanium dioxide (E171), macrogol MW 8000 (E1521) and magnesium stearate (E572), iron oxide yellow (E172) (74mg only) and FD&C blue#2/indigo carmine aluminium lake (E132) (74mg only).

What Lurasidone looks like and contents of the pack

Lurasidone 18.5mg tablets are white to off-white, film-coated round tablets with 6.1mm diameter, with "LO" on one side.

Lurasidone 37mg tablets are white to off-white, film-coated round tablets with 8.1mm diameter, with "LI" on one side.

Lurasidone 74mg tablets are pale green to green, film-coated oval tablets with 12.1x7.1mm dimension, with "LH"on one side.

The tablets are supplied in OPA/AI/PVC/AI blister comprising of aluminium forming foil and aluminium sealing foil in a cardboard box containing 14, 28, 30, 56, 90 or 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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ASPIRE® PHARMA

Packaging Information:

Product Name:	Lurasidone film-coated tablets
PL No:	35533/0209-11
Dimensions:	290mm x 400mm
Type:	Leaflet
Version No:	3.2
Date amended:	8.9.26
Font:	Tahoma
Average font size:	8.5pt
Reason for change:	small text amendment to embossing information
Software:	Adobe Indesign CS

Colour:
Pantone:

PMS Black