

PATIENT INFORMATION LEAFLET

Lurasidone 20/40/80 mg Film-Coated Tablets

LUCIFER 20/40/80

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.

What is in this leaflet:

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

1. What Lucifer is and what it is used for

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2. What you need to know before you take LUCIFER
3. How to take LUCIFER
4. Possible side effects
5. How to store LUCIFER
6. Contents of the pack and other information

1. What LUCIFER is and what it is used for

LUCIFER 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. LUCIFER works by blocking receptors in the brain to which the substances dopamine and serotonin attach. By blocking their receptors, LUCIFER helps to normalise the activity of the brain, reducing the symptoms of schizophrenia.

2. What you need to know before you take LUCIFER

Do not take LUCIFER:

If you are allergic to LUCIFER or any of the other ingredients of this medicine
If you are taking medicines which may affect the level of LUCIFER in your blood such as:

- ❖ Medicines for fungal infections such as itraconazole, ketconazole (except as a shampoo), Posaconazole or Voriconazole
- ❖ Medicines for an infection such as the antibiotic Clarithromycin or Telithromycin
- ❖ Medicines for HIV infections such as Cabicitab, Indinavir, Nelfinavir, Ritonavir, and Saquinavir
- ❖ Medicines for chronic hepatitis such as Boceprevir and Telaprevir
- ❖ Medicines for depression: Nefazodone
- ❖ 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 LUCIFER, or during treatment, especially if you have:

- ❖ Suicidal thoughts or behavior
- ❖ Parkinson's disease or dementia
- ❖ Ever been diagnosed with a condition whose symptoms include high temperature and muscle stiffness or if you have ever experienced rigidity, tremors or problems moving or abnormal movements of the tongue or face. 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 male (gynecomastia), milky nipple discharge (galactorrhea), absence of menstruation (amenorrhoea) or erectile dysfunction
- ❖ Diabetes or are prone to diabetes
- ❖ Decreased kidney function and liver function
- ❖ An increase in your weight
- ❖ Blood pressure dropping upon you 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 LUCIFER can lead to serotonin syndrome, a potentially life-threatening condition.

Children and adolescents

Do not give this medicine to children below 13 years of age.

Other medicines and LUCIFER

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 LUCIFER 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, Astemizole, Clozapine, Pimozide, Quinidine and Bepridil.
- ❖ Medicines containing Buprenorphine or opioids or anti-depressants such as Mocllobemide, Tranylcypromine, Citalopram, Escitalopram, Fluoxetine, Fluvoxamine, Paroxetine, Sertraline, Duloxetine, Venlafaxine, Amitriptyline, Doxepin or Trimepramine. These medicines may interact with LUCIFER 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.
- ❖ The following medicines may increase the level of LUCIFER in your blood: Diltiazem, Erythromycin, Fluconazole and Vinorelbine
- ❖ The following medicines may decrease the level of LUCIFER in your blood: Amprenavir, Efavirenz, Etravirine, Aprepitant, Amodiafinil, Modafinil, Bosentan, Nafacillin, Prednisone and Rifunamide.

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

LUCIFER 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 and breast-feeding

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.

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 LUCIFER in the last trimester (last three months) of their pregnancy:

- ❖ Shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you should contact your doctor.

Driving and using machines

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

LUCIFER contains sodium

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

3. How to take LUCIFER

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
- ❖ If you have kidney or liver problems.

Schizophrenia

The recommended starting dose of LUCIFER is 40 mg once daily. Initial dose titration is not required.

LUCIFER has been shown to be effective in a dose range of 40 mg/day to 120 mg/day.

In the 6-week controlled trials, there was no suggestion of added benefit with the 120 mg/day dose, but there was a dose-related increase in certain adverse reactions. Therefore, the maximum recommended dose is 80 mg/day.

Administration Instructions

LUCIFER should be taken with food (at least 350 calories).

Dosage in Special Populations

Dosage adjustments are not recommended on the basis of age, gender, and race. Dose adjustment is recommended in moderate and severe renal impairment patients. The dose in these patients should not exceed 40 mg/day. Dose adjustment is recommended in moderate and severe hepatic impairment patients. The dose in these patients should not exceed 40 mg/day.

Dosing recommendation for patients taking LUCIFER concomitantly with potential CYP3A4 inhibitors:
When coadministration of LUCIFER with a moderate CYP3A4 inhibitor such as diltiazem is considered, the dose should not exceed 40 mg/day. LUCIFER should not be used in combination with a strong CYP3A4 inhibitor (e.g., ketoconazole).

Dosing recommendation for patients taking LATUDA concomitantly with potential CYP3A4 inducers:
LUCIFER should not be used in combination with a strong CYP3A4 inducer (e.g., rifampin)

How to take LUCIFER tablets

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 LUCIFER 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 heart beats.

If you forget to take LUCIFER

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 LUCIFER

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 or 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. 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 dots in the veins especially in the legs, 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, Insomnia

Common (may affect up to 1 in 10 people):

- ❖ Parkinsonism
- ❖ 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 and increased blood pressure
- ❖ Dizziness
- ❖ Muscle spasms, stiffness
- ❖ Vomiting (being sick), Diarrhoea, Back pain, Abdominal pain
- ❖ Rash and itching
- ❖ Indigestion
- ❖ Dry mouth or excess saliva
- ❖ Somnolence, tiredness, agitation and anxiety
- ❖ Weight gain
- ❖ Reduced appetite
- ❖ Increase in creatine phosphokinase seen in blood tests
- ❖ Increase in creatinine seen in blood tests.

Uncommon (may affect up to 1 in 100 people):

- ❖ Slurred speech, Nightmares, Temporary loss of consciousness, Blurred vision and Sweating.
- ❖ Difficulty swallowing, Irritation to lining of stomach and Gas (flatulence).
- ❖ Sudden feelings of anxiety, Convulsion (fits), Spinning sensation
- ❖ Chest pain, Muscle aches, Joint pains, Problems walking
- ❖ Abnormal nerve impulses in the heart, Slow heart rate and Rigid posture
- ❖ Increased blood prolactin, increased blood glucose, increase in some liver enzymes, seen in blood tests
- ❖ Blood pressure dropping upon standing up which may cause fainting.
- ❖ Common cold
- ❖ Hot flush and 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
- ❖ Lack of energy (lethargy)
- ❖ Neck pain
- ❖ Problems with erections
- ❖ Painful or absence of menstrual periods
- ❖ Reduced levels of red blood cells

Rare (may affect up to 1 in 1,000 people):

- ❖ Rhabdomyolysis
- ❖ Increase in eosinophils and Reduced levels of white blood cells
- ❖ Swelling beneath the skin surface
- ❖ Deliberate injury to oneself
- ❖ Cerebrovascular accident and Sudden death.
- ❖ Kidney failure
- ❖ Breast pain, milk secretion from breasts

Not known (frequency cannot be estimated from the available data):

- ❖ Reduced levels of a subgroup of white blood cells
- ❖ 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

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
- ❖ Symptoms of schizophrenia and Parkinsonism, Difficulty in attention, Abnormal involuntary movements
- ❖ Spinning sensation
- ❖ Abnormal muscle tone, including torticollis and involuntary upward deviation of the eyes,
- ❖ Fast heartbeat

- ❖ Difficulty in emptying the bowels, Vomiting (being sick), Dry mouth or excess saliva, Sweating and Muscle rigidity
- ❖ Problems with erections
- ❖ Increase in creatine phosphokinase and blood prolactin

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 behavior, Apathy, Confusional state, Depressed mood, Separation of normal mental processes
- ❖ Homocidal thoughts, Intentional overdose and Difficulty in sleeping
- ❖ Sexual desire increased or decreased, Sexual dysfunction, Difficulty in ejaculation
- ❖ Lack of energy, Obsessive thoughts, feeling of acute and disabling anxiety
- ❖ Engage in involuntary movements that serve no purpose
- ❖ Hyperactivity of the muscles in the body (hyperkinesia), inability to rest
- ❖ Uncontrollable urge to move legs, uncontrollable movements of mouth, tongue and limbs
- ❖ Sleep disorder, Deliberate suicidal thoughts, Thinking abnormal
- ❖ Unsteadiness (spinning sensation), Alteration of taste, Memory impairment
- ❖ Abnormal skin sensation (paraesthesia)
- ❖ Feeling like with 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 deficiency in secretion of saliva, Diarrhoea, Indigestion, Lip dry, Toothache
- ❖ Partial or complete absence of hair, hair growth abnormal
- ❖ Rash, urticarial, Muscle spasms/aches and stiffness, Joint pains, pain in arms and legs, pain in jaw
- ❖ Presence of foalium in urine, presence of protein in urine, a marker of kidney function
- ❖ Pain or difficulty when passing urine, frequent urination, renal disorder
- ❖ Abnormal breast enlargement, breast pain, milk secretion from breasts
- ❖ Menstruation absent or irregular
- ❖ Make uncontrolled noises and movements (Tourette's disorder)
- ❖ Chills, Problems walking, Chest pain, Fever, Malaise
- ❖ 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, increased blood insulin, increase in some liver enzymes, seen in blood tests
- ❖ Increased or decreased blood testosterone, increased blood thyroid stimulating hormone
- ❖ Electrocardiogram alterations
- ❖ Decreased hemoglobin, reduced levels of white blood cells (which fight infection)

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.

5. How to store LUCIFER

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 carton and blister after EXP. The expiry date refers to the last day of that month.

LUCIFER tablets should be kept in their original blister and outer carton (to protect them from light and moisture).

Store in a dry place at or below 30°C.

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 LUCIFER contains

The active substance is Lurasidone.

LUCIFER 20

Each film coated tablet contains:
Lurasidone Hydrochloride 20mg
Colours: Titanium Dioxide

LUCIFER 40

Each film coated tablet contains:
Lurasidone Hydrochloride 40mg
Colours: Titanium Dioxide

LUCIFER 80

Each film coated tablet contains:
Lurasidone Hydrochloride 80mg
Colours: Tartrazine Lake, Brilliant Blue & Titanium Dioxide

What LUCIFER looks like and contents of the pack

LUCIFER 20 tablets are White, Round, Biconvex and Film Coated Tablets with deep breakline on one side. Tablets are packed into Alu-Alu Blister. The pack size is 10 x 10 in a printed paper carton.

LUCIFER 40 tablets are White, Round, Biconvex and Film Coated Tablets with deep breakline on one side. Tablets are packed into Alu-Alu Blister. The pack size is 10 x 10 in a printed paper carton.

LUCIFER 80 tablets are Green, Round, Biconvex and Film Coated Tablets with deep breakline on one side. Tablets are packed into Alu-Alu Blister. The pack size is 10 x 10 in a printed paper carton.



Manufactured by :
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