**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:**

**S5**

**LATUMAK 20 mg** (film coated tablet)

**LATUMAK 40 mg** (film coated tablet)

**LATUMAK 60 mg** (film coated tablet)

**LATUMAK 80 mg** (film coated tablet)

**LATUMAK 120 mg** (film coated tablet)

Lurasidone

Sugar free

**Read all of this leaflet carefully before you start taking LATUMAK**

- 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.
- **LATUMAK** 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 LATUMAK is and what it is used for

LATUMAK contains lurasidone hydrochloride.

LATUMAK 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. 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such as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech and behaviour and emotional flatness.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 LATUMAK

**Do not take LATUMAK:**

- If you are allergic to lurasidone or any of the other ingredients of this medicine, listed in section 6.
- If you are taking medicines for fungal infections such as itraconazole, ketoconazole (except as a shampoo), posaconazole or voriconazole medicines for seizures such as carbamazepine, phenobarbital and phenytoin herbal medicine for depression, St John's wort (*Hypericum perforatum*)

**Warnings and precautions**

Talk to your doctor before taking LATUMAK 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 male (gynecomastia), milky nipple discharge (galactorrhoea), absence of menstruation (amenorrhea) or erectile dysfunction
- diabetes or are prone to diabetes
- an increase in your weight
- Blood pressure dropping upon your standing up which may cause fainting.
- Opioids 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 **LATUMAK** can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and **LATUMAK**”).

**Other medicines and LATUMAK**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking any of the following medicines:

- any medicines that also work in the brain, as their effects could be additive in a negative way with the effects of **LATUMAK** 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 to

treating psychiatric illnesses), quinidine (used for treating heart conditions), bepridil (used for treating chest pain).

- medicines containing buprenorphine (used for treating opioids dependence) or opioids (used for treating sever pain) or anti-depressants such as moclobemide, tranylcypromine, citalopram,
- escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, duloxetine, venlafaxine, amitriptyline, doxepine, or trimipramine. These medicines may interact with **LATUMAK** 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 **LATUMAK**.

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 **LATUMAK**.

**LATUMAK with food and drink:**

**LATUMAK** should be taken with food.

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

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

**Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking LATUMAK.

You should not use **LATUMAK** if you are pregnant.

You should not use **LATUMAK** if you are breastfeeding your baby.

**Driving and using machines**

Do not drive or use machines until you know how **LATUMAK** affects you. Sleepiness, dizziness and vision problems may occur during treatment with **LATUMAK** (see section 4, Possible side effects).

It is not always possible to predict to what extent **LATUMAK** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **LATUMAK** affects them.

**3. How to take LATUMAK**

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

Always take **LATUMAK** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Your dose will be decided on by your doctor.

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

**If you take more LATUMAK than you should**

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

**If you forget to take LATUMAK**

It is important to take your **LATUMAK** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

**If you stop taking LATUMAK**

If **LATUMAK** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **LATUMAK** for as long as your doctor has prescribed.

**4. Possible side effects**

**LATUMAK** can have side effects.

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

If any of the following happens, stop taking **LATUMAK** and tell your doctor immediately or go to the casualty department at your nearest hospital:

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).

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.

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.

These are all very serious side effects. If you have them, you may have had a serious reaction to **LATUMAK**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Frequently occurring:*

- feeling of restlessness and inability to sit still
- insomnia
- 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.
- Dizziness
- somnolence, tiredness, agitation and anxiety
- nausea (feeling sick)
- vomiting (being sick)
- diarrhoea
- indigestion
- dry mouth or excess saliva
- abdominal pain
- weight gain
- reduced appetite
- back pain
- fast heartbeat
- increased blood pressure
- rash and itching
- muscle spasms and stiffness
- increase in creatine phosphokinase (an enzyme in muscles) seen in blood tests
- Increase in creatinine (a marker of kidney function) seen in blood tests.
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*Less frequently occurring:*

- slurred speech
- nightmares
- sudden feelings of anxiety
- convulsion (fits)
- temporary loss of consciousness
- problems walking

- rigid posture
- blood pressure dropping upon standing up which may cause fainting
- uncontrollable movements of mouth, tongue and limbs (tardive dyskinesia)
- deliberate injury to oneself
- lack of energy (lethargy)
- cerebrovascular accident
- difficulty swallowing
- irritation to lining of stomach
- gas (flatulence)
- chest pain
- abnormal nerve impulses in the heart
- slow heart rate
- hot flush
- blurred vision
- Sweating
- swelling beneath the skin surface (angioedema)
- muscle aches
- joint pains
- neck pain
- 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
- Pain when passing urine.
- kidney failure
- increased blood prolactin, increased blood glucose (blood sugar), increase in some liver enzymes, seen in blood tests
- problems with erections
- painful or absence of menstrual periods

- breast pain, milk secretion from breasts
- sudden death
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma (hyponatremia).
- 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:

*Frequently:*

- feeling of restlessness and inability to sit still
- headache
- sleepiness
- abnormal dreams
- difficulty in sleeping, tension, agitation, anxiety and irritability
- 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
- 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)
- physical weakness, tiredness

- spinning sensation
- nausea (feeling sick)
- reduced or increased appetite
- difficulty in emptying the bowels (constipation)
- dry mouth or excess saliva
- vomiting (being sick)
- fast heartbeat
- sweating
- muscle rigidity
- problems with erections
- increase in blood prolactin (a hormone), seen in blood tests
- increase in creatine phosphokinase (an enzyme in muscles) seen in blood tests
- weight gain or loss
-

*Less frequently*

- hypersensitivity
- common cold, infection of throat and nose
- decreased activity of thyroid, inflammation of thyroid
- 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
- decreased haemoglobin, reduced levels of white blood cells (which fight infection) seen in blood tests
- 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)
- memory impairment
- abnormal skin sensation (paraesthesia)
- feeling like with a tight band around head (tension headache), migraine
- intentional overdose
- alteration of taste
- diarrhoea
- indigestion
- lip dry

- abdominal pain or disturbance
- absence of or deficiency in secretion of saliva
- toothache
- difficulty of the eyes in focusing, vision blurred
- palpitations, alterations in heart rhythm
- blood pressure dropping upon standing up which may cause fainting
- increased blood pressure
- chest pain
- electrocardiogram alterations
- increased sensitivity of hearing
- partial or complete absence of hair, hair growth abnormal
- rash, urticaria
- muscle spasms and stiffness, muscle aches
- joint pains, pain in arms and legs, pain in jaw
- problems walking
- 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
- malaise
- fever

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

Should your general health worsen or if you experience any untoward effects while taking **LATUMAK**, please consult your healthcare provider for advice.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 **LATUMAK.**

**5. How to store LATUMAK**

Store at or below 30 °C.

KEEP OUT OF THE REACH OF CHILDREN.

Store in the original package / container.

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister / label/ carton bottle.

Return all unused medicine to your pharmacist.

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

**6. Contents of pack and other information**

**What LATUMAK contains**

The active ingredient is lurasidone hydrochloride.

Sugar free

The other ingredients are:

Croscarmellose sodium

Hydroxypropyl methylcellulose

Colloidal silicon dioxide

Magnesium stearate

Instacoat Universal green and white which contains:

- Hypromellose

- Polyethylene glycol
- Titanium dioxide
- Yellow iron oxide
- FD and C Blue No. 2 Al lake
- Croscarmellose sodium
- Hydroxypropyl methylcellulose

**What LATUMAK looks like and contents of the pack**

LATUMAK 20 mg: L White to off white, round biconvex, film coated tablets, debossed with “F3” on one side and plain on other side

LATUMAK 40 mg: White to off white, round biconvex, film coated tablets, debossed with “F4” on one side and plain on other side

LATUMAK 60 mg: White to off white, capsule biconvex, film coated tablets, debossed with “F5” on one side and plain on other side

LATUMAK 80 mg: Pale green, oval, biconvex, film coated tablets, debossed with “F6” on one side and plain on other side

LATUMAK 120 mg: White to off white, oval, biconvex, film coated tablets, debossed with “F7” on one side and plain on other side

**Contents of the pack:**

**Blister pack:**

Tablets are packed in a blister containing plain aluminium foil with heat seal lacquered as the lidding material and clear PVC/PVDC as the forming material. The blister is packed in an outer carton.

**Blister pack cold form:**

Tablets are packed in a blister containing plain aluminium foil with heat seal lacquered as the lidding material and cold form laminate as the forming material. The blister is packed in an outer carton.

Pack sizes include 14, 28, 56, 84, 90, &100

**HDPE container:**

Tablets are packed in Container, round, white, HDPE, 60 cc HW, 33mm neck finish with 33 mm Closure, child resistant, with pulp and white printed Heat Seal Liner.

Tablets are packed in Container, round, white, HDPE,75 cc HW, 38-400 neck finish with 38 mm Closure, child resistant, with pulp and white printed Heat Seal Liner

Pack size include 30, 90.

Not all pack sizes may be marketed.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

**MACLEODS PHARMACEUTICALS SA (PTY) LTD**

Ground Floor, Block 1,

Bassonia Estate Office Park (East),

1 Cussonia Drive,

Bassonia Rock Ext 12

Alberton

Gauteng

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**LATUMAK 20 mg:** 57/1.2/0772.767

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**LATUMAK 80 mg:** 57/1.2/0775.770

**LATUMAK 120 mg:** 57/1.2/0776.771

Access to the corresponding Professional Information

The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169