Dimensions: 400 x 360 mm (Front Side)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

MAKTUDA 20 mg (film coated tablet)
MAKTUDA 40 mg (film coated tablet)
MAKTUDA 60 mg (film coated tablet)
MAKTUDA 80 mg (film coated tablet)
MAKTUDA 120 mg (film coated tablet)
Lurasidone
Sugar free

Read all of this leaflet carefully before you start taking MAKTUDA

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

1. What MAKTUDA is and what it is used for

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as hearing things, seeing or sensing things that are not there, mistaken beliefs, unusual suspiciousness, becoming withdrawn, incoherent speech and behaviour and emotional flatness.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

Do not take MAKTUDA:
- 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 **MAKTUDA** 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 **MAKTUDA** can lead to serotonin syndrome, a potentially life- threatening condition (see "**Other medicines and MAKTUDA**").

Other medicines and MAKTUDA
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 **MAKTUDA** 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, doxepine, or trimipramine. These medicines may interact with **MAKTUDA** 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 **MAKTUDA.**

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 **MAKTUDA.**

MAKTUDA with food and drink:

MAKTUDA should be taken with food.
Alcohol should be avoided when taking **MAKTUDA.** This is because alcohol will have an additive negative effect.
Do not drink grapefruit juice while you are taking **MAKTUDA.** Grapefruit can affect the way **MAKTUDA** 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 **MAKTUDA.**

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

Driving and using machines
Do not drive or use machines until you know how **MAKTUDA** affects you. Sleepiness, dizziness and vision problems may occur during treatment with **MAKTUDA** (see section 4, **Possible side effects**). It is not always possible to predict to what extent **MAKTUDA** 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 **MAKTUDA** affects them.

3. How to take MAKTUDA

Do not share medicines prescribed for you with any other person.
Always take **MAKTUDA** 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 **MAKTUDA** is too strong or too weak, talk to your doctor or pharmacist.

If you take more MAKTUDA 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 MAKTUDA
It is important to take your **MAKTUDA** 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 MAKTUDA

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

4. Possible side effects

MAKTUDA can have side effects.
Not all side effects reported for **MAKTUDA** are included in this leaflet. Should your general health worsen or if you experience any unlisted effects while taking **MAKTUDA**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **MAKTUDA** 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 **MAKTUDA.** 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

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 **MAKTUDA,** 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 **MAKTUDA.**

5. How to store MAKTUDA

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 MAKTUDA contains
The active ingredient is lurasidone hydrochloride.
Sugar free
The other ingredients are:
Mannitol
Croscarmellose sodium
Hydroxypropyl methylcellulose
Pregelatinized starch
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

What MAKTUDA looks like and contents of the pack
MAKTUDA 20 mg: White to off-white, round, biconvex, film coated tablets debossed with "JP" on one side and "20" on other side.
MAKTUDA 40 mg: White to off-white, round, biconvex, film coated tablets debossed with "JP" on one side and "40" on other side.
MAKTUDA 60 mg: White to off-white, capsule, biconvex, film coated tablets debossed with "JP" on one side and "60" on other side.
MAKTUDA 80 mg: Green to greenish yellow, oval, biconvex, film coated tablets, debossed with "JP" on one side and "80" on other side.
MAKTUDA 120 mg: White to off-white, oval, biconvex, film coated tablets debossed with "JP" on one side and "120" on other side.

Contents of the pack:
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 10, 14, 28, 30, 56, 84, 90, &100

HDPE container:
60 cc round, white, HDPE container with 33 mm neck finish, closed with a 33 mm white closure, with pulp and white printed heat seal liner.
75 cc round, white, HDPE container with 38 mm neck finish, closed with a 38 mm white closure, 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

This leaflet was last revised in
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Registration numbers
MAKTUDA 20 mg: 57/1.2/0772.767
MAKTUDA 40 mg: 57/1.2/0773.768
MAKTUDA 60 mg: 57/1.2/0774.769
MAKTUDA 80 mg: 57/1.2/0775.770
MAKTUDA 120 mg: 57/1.2/0776.771

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodssaproducts.co.za or contact 011 682 1169

MAKTUDA
20/40/60/80/120 mg
PM04317401

Dimensions: 400 x 360 mm (Back Side)

360 mm

400 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S5

MAKTUDA 20 mg (filmbedekte tablet)
MAKTUDA 40 mg (filmbedekte tablet)
MAKTUDA 60 mg (filmbedekte tablet)
MAKTUDA 80 mg (filmbedekte tablet)
MAKTUDA 120 mg (filmbedekte tablet)
Lurasidoon
Suikervry

Lees hierdie hele inligtingstuk noukeurig deur voordat jy MAKTUDA begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **MAKTUDA** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **MAKTUDA** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **MAKTUDA** neem
3. Hoe om **MAKTUDA** te neem
4. Moontlike newe-effekte
5. Hoe om **MAKTUDA** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat MAKTUDA is en waarvoor dit gebruik word

MAKTUDA bevat lurasidoonhidrochloried.
MAKTUDA behoort aan 'n groep van medisyne wat antipsigotika genoem word.
Dit word gebruik om simptome van skisofrenie in volwassenes (ouderdom 18 jaar en ouer) en adolessente 13 -17 jarige ouderdom, te behandel. Skisofrenie is 'n afwyking met simptome soos om dinge te hoor, te sien of goed aan te voel wat nie daar is nie, verwarde oortuigings, ongewone agterdog, teruggetrokke te raak, onsamehangende spraak en gedrag en emosionele platheid. Mense met hierdie afwyking kan ook depressief, angstig, skuldig of gespanne voel. Hierdie medisyne word gebruik om jou simptome van skisofrenie te verbeter.

2. Wat jy behoort te weet voordat jy MAKTUDA neem

Moet nie MAKTUDA neem nie:
- Indien jy allergies is vir lurasidoon of enige van die ander bestanddele van hierdie meditsyne, gelys in afdeling 6.
- Indien jy medisyne gebruik vir swambesmetting (ketokonasool, ketokonasool (behalwe as 'n sjampoe), posakonasool of vorikonasool, middels vir aanvalle soos karbamasepien, fenobarbitoon en fenitoïen, kruie middel vir depressie, St Johannes kruid (*Hypericum perforatum*).

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy **MAKTUDA** neem as jy enige van die onderstaande het
- selfmoordgedagtes of -gedrag
- Parkinson se siekte of demensie
- ooit gediagnoseer is met 'n toestand wat simptome insluit van hoë temperatuur en spierstyfheid (ook bekend as maligne neuroleptiese sindroom) of as jy al ooit stywheid, bewing of probleme met beweging (ekstrapiramidale simptome) of abnormale bewegings van die long of gesig (tardiewe diskinesie) ervaar het. Jy moet daarvan bewus wees dat hierdie toestande deur hierdie medisyne veroorsaak kan word
- Hartsiekte of behandeling vir hartsiekte wat maak dat jy geneig is tot lae bloeddruk of het 'n familiegeskiedenis van onreëlmatige hartdop (insluitend QT-verlenging)
- 'n geskiedenis van aanvalle (stuipe) of epilepsie
- 'n geskiedenis van bloedklonte, of as iemand anders in jou familie 'n geskiedenis van bloedklonte het, aangesien medisyne vir skisofrenie geassosieer is met die vorming van bloedklonte
- vergrote borste in mans (ginekomastie), melkerige tepelafskeiding (galaktoree), afwesigheid van menstruasie (amenoree) of erektiele disfunksie
- diabetes of geneig is tot diabetes
- 'n toename in jou gewig
- Bloeddruk daal wanneer jy opstaan, wat kan veroorsaak dat jy flou word.
- Opioïede afhanklikheid (behandel met buprenorfien) of erge pyn (behandel met opioïede) of depressie of ander toestande wat met antidepressante behandel word. Die gebruik van hierdie medisyne saam met **MAKTUDA** kan lei tot serotoninesindroom. 'n potensieel lewensgevaarlike toestand (sien "**Ander medisyne en MAKTUDA**")

Ander medisyne en MAKTUDA
Vertel altyd jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker as jy enige van die volgende medisyne neem:
- enige medisyne wat ook in die brein werk, aangesien die effekte daarvan op 'n negatiewe manier kan meewerk met die effekte van **MAKTUDA** op jou brein.
- medisyne wat bloeddruk verlaag, aangesien hierdie medisyne ook bloeddruk kan verlaag.
- medisyne vir Parkinson se siekte en rustelose bene sindroom (bv. levodopa) omdat hierdie medisyne hul effekte kan verminder.
- medisyne wat ergot-alkaloïedderivate bevat (gebruik vir die behandeling van migraine), en ander medisyne insluitend terfenadien en astemisool (wat gebruik word vir die behandeling van hooikoors en ander allergiese toestande), sisapried (gebruik vir die behandeling van spysverterings probleme), pimosied (gebruik vir behandeling van pelgiatriese siektes), kinidien (gebruik vir behandeling van hartloestande), bepridil (gebruik vir behandeling van borskaspyn).
- medisyne wat buprenorfien bevat (gebruik vir behandeling van opioïede afhanklikheid) of opioïede (gebruik vir die behandeling van erge pyn) of anti-depressante soos moklobemied, tranielsipromien, sitalopram, essitalopram, fluoksetien, fluvoksamien, paroksetien, sertralien, duloksetien, venlafaksien, amitriptilliën, doksepien, of trimipramien. Hierdie medisyne kan interaksie met **MAKTUDA** hê en jy kan simptome ervaar soos onwillekeurige, ritmiese sametrekkings van spiere, insluitend die spiere wat beweging van die oog beheer, aglasie, hallusinasies, koma, oormatige sweet, bewing, oordrywing van reflekse, verhoogde spierspanning, liggaams temperatuur bo 38°C. Kontak jou dokter wanneer jy sulke simptome ervaar.

Vertel jou dokter as jy enige van hierdie medisyne gebruik aangesien jou dokter dalk die dosis van daardie medisyne sal moet verander tydens behandeling met **MAKTUDA.**

Die volgende medisyne kan die vlak van lurasidoon in jou bloed verhoog:
- diltiasem (om hoë bloeddruk te behandel)
- eritromisien (om infeksies te behandel)
- flukonasool (om swambesmetting te behandel)
- Verapamil (om hoë bloeddruk of borskaspyn te behandel)

Die volgende medisyne kan die vlak van lurasidoon in jou bloed verlaag:
- amprenavir, efavirens, etravirien (om MIV-infeksie te behandel)
- aprepitant (om naarheid en braking te behandel)
- armodafinil, modafinil (om slaperigheid te behandel)
- bosentan (om hoë bloeddruk of ulkusse van die vingers te behandel)
- nafsillin (om infeksies te behandel)
- prednisoon (om inflammatoriese siektes te behandel)
- Rifinamied (om aanvalle te behandel)

Vertel jou dokter as jy enige van hierdie medisyne neem, aangesien jou dokter moontlik jou dosis van **MAKTUDA** kan verander.

MAKTUDA met kos en drank:
MAKTUDA moet saam met kos geneem word.
Alkohol moet vermy word wanneer **MAKTUDA** geneem word. Dit is omdat alkohol 'n bykomende negatiewe effek sal hê.
Moet nie pomelosap drink terwyl jy **MAKTUDA** neem nie. Pomelo kan die manier waarop **MAKTUDA** werk, affekteer.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **MAKTUDA** neem.

Jy moet nie **MAKTUDA** gebruik indien jy swanger is nie.
Jy moet nie **MAKTUDA** gebruik indien jy jou baba borsvoed nie.
Bestuur en gebruik van masjinerie
Moet nie bestuur of masjiene gebruik totdat jy weet hoe **MAKTUDA** jou affekteer nie. Slaperigheid, duiseligheid en probleme met sig kan voorkom tydens behandeling met **MAKTUDA** (sien afdeling 4, **Moontlike newe-effekte**).
Dit is nie altyd moontlik om te voorspel tot watter mate **MAKTUDA** met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie in die bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is van die mate waarin **MAKTUDA** hulle affekteer nie.

3. Hoe om MAKTUDA te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **MAKTUDA** presies soos jou dokter jou beveel het. Jy moet jou dokter of apteker raadpleeg indien jy nie seker is nie.

Jou dokter sal oor die dosis besluit.

Indien jy die indruk het dat die effek van **MAKTUDA** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer MAKTUDA neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om MAKTUDA te neem
Dit is belangrik om jou **MAKTUDA** gereeld op dieselfde tyd elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse op dieselfde tyd neem, om op te maak vir 'n vergete dosis nie.

Indien jy ophou om MAKTUDA te neem
Wanneer **MAKTUDA** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **MAKTUDA** vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

MAKTUDA kan newe-effekte hê.
Nie alle newe-effekte wat vir **MAKTUDA** aangemeld is, is in hierdie inligtingstuk ingeskuit nie. Sou jou algemene gesondheid vererger of indien jy enige ongunstige effekte ervaar terwyl jy **MAKTUDA** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **MAKTUDA** te gebruik en kontak onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:

'n Erge allergiese reaksie wat voorkom as koors, geswelde mond, gesig, lip of tong, kort van asem, gejeuk, veluitslag en soms 'n daling in bloeddruk (hipersensitiwiteit).

'n Ernstige uitslag met blase wat die vel, mond, oë en geslagsdele aantas (Stevens-Johnson sindroom). Hierdie reaksie kom voor met onbekende freikwensie.

Koors, sweet, spierstyfheid en afname in bewussyn. Hierdie kan simptome wees van 'n toestand bekend as maligne neuroleptiese sindroom.

Bloedklonte in die are, veral in die bene (simptome sluit swelling, pyn en rooiheid in die been in), wat deur bloedvate na die longe kan beweeg, wat borskaspyn en probleme met asemhaling kan veroorsaak. Indien jy enige van hierdie simptome opmerk, soek onmiddellik mediese advies.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige reaksie op **MAKTUDA** gehad. Jy benodig moontlik dringende mediese aandag of hospitalisering.

Vertel jou dokter indien jy enige van die volgende opmerk:
Kom gereeld voor:
- gevoel van rusteloosheid en onvermoë om stil te sit
- Parkinsonisme: hierdie is 'n mediese term wat baie simptome beskryf wat insluit toename in speekselafskeiding of waterige mond, kwyl, trekkings wanneer die ledemate buig, stadig, verminderde of ingekorte liggaamsbewegings, geen uitdrukking in die gesig, spierstrakheid, stywe nek, spierstyfheid, klein, skuifel, haastige tree en gebrek aan normale armbewegings wanneer jy loop, aanhoudende oogknip in reaksie op lig van die voorkop ('n abnormale refleks)
- Spraakprobleme, ongewone spierbewegings; 'n versameling van simptome bekend as ekstrapiramidale simptome (EPS) wat tipies ongewone dooiloose onwillekeurige spierbewegings sal behels
- Duiseligheid
- slaperigheid, moegheid, rusteloosheid en angstigheid
- naarheid (siek voel)
- braking (siek wees)
- diarree
- slegte spysvertering
- droë mond of oortollige speeksel
- abdominale pyn
- gewig optel
- verminderde eetlus
- rugpyn
- vinnige hartdop
- verhoogde bloeddruk
- uitslag en gejeuk
- spierspasmas en stywheid
- toename in kreatienfosfokinase ('n ensiem in spiere) wat in bloedtoetse gesien word
- Toename in kreatinien ('n merker van nierfunksie) wat in bloedtoetse gesien word

Kom minder gereeld voor:
- sleepspraak
- nagmerries
- sikkelike gevoel van angstigheid
- stuiptrekkings (aanvalle)
- tydelike verlies van bewussyn
- probleme om te loop
- rigiede postuur
- bloeddruk daal wanneer jy opstaan, wat kan veroorsaak dat jy flou word
- onbeheerbare bewegings van mond, tong en ledemate (laatdiskinesie)
- openlike besering aan jouself
- gebrek aan energie (letargie)
- serebrovaskulêre ongeluk
- sukkel om te sluk
- irritasie van die voering van die maag
- gas (winderigheid)
- borskaspyn
- abnormale senuwee-impulse in die hart
- stadige harttempo
- warm gloede
- dowwe visie
- Sweet
- swelling onder die veloppervlak (angioödeem)
- spierpyne
- gewrigspyne
- nek pyn
- Rabdomiolise wat die afbreek van spiervesels is wat lei tot die vrystelling van spierveselinhoud (mioglobien) in die bloedstroom, gesien as spierpyn, siek wees, verward wees, 'n abnormale hartdop en -ritme, en moontlik donker urine
- Pyn wanneer jy urine passeer
- nierversaking
- verhoogde prolaktien in die bloed, verhoogde bloedglukose (bloedsuiker), toename in sommige lewer ensieme, gesien in bloedtoetse
- probleme met ereksies
- pynlike of afwesige menstruele tydperke
- borspyn, melkafskeiding vanuit borste
- skielike dood
- Lae vlakke van natrium in die bloed wat moegheid en verwarring, spiertrekkings, aanvalle en koma (hiponatremie) kan veroorsaak
- In bejaarde mense met demensie is 'n klein toename in die aantal sterftes vir pasiënte wat medisyne vir skisofrenie neem in vergelyking met diegene wat nie hierdie medisyne ontvang nie, aangemeld

Die volgende newe-effekte kan in adolessente voorkom:
Gereeld:
- gevoel van rusteloosheid en onvermoë om stil te sit
- hoofpyn
- slaperigheid
- abnormale drome
- probleme met slaap, spanning, rusteloosheid, angstigheid en prikkelbaarheid
- depressie
- psigotiese versteuring: dit is 'n mediese term wat baie geestesiektes beskryf wat abnormale denke en persepsies veroorsaak; mense met psigoses verloor kontak met die werklikheid
- simptome van skisofrenie
- probleme met aandag
- abnormale onwillekeurige bewegings (diskinesie)
- abnormale spiertonus, insluitend *torticollis* en onwillekeurige opwaartse afwyking van die oë
- Parkinsonisme: hierdie is 'n mediese term wat baie simptome beskryf wat insluit toename in speekselafskeiding of waterige mond, kwyl, trekkings wanneer die ledemate buig, stadig, verminderde of ingekorte liggaamsbewegings, geen uitdrukking in die gesig, spierstrakheid, stywe nek, spierstyfheid, klein, skuifel, haastige tree en gebrek aan normale armbewegings wanneer jy loop, aanhoudende oogknip in reaksie op lig van die voorkop ('n abnormale refleks)
- fisiese swakheid, moegheid
- draai sensasie
- naarheid (siek voel)
- verminderde of verhoogde eetlus
- probleme om die derms leeg te maak (hardlywigheid)
- droë mond of oortollige speeksel
- braking (siek wees)
- vinnige hartdop
- sweet
- spierstyfheid
- probleme met ereksies
- toename in bloedprolaktien ('n hormoon), gesien in bloedtoetse
- toename in kreatienfosfokinase ('n ensiem in spiere) wat in bloedtoetse gesien word
- gewigstoename of -verlies

Minder gereeld
- hipersensitiwiteit
- gewone verkoue, infeksie van keel en neus
- verminderde aktiwiteit van skildklier, ontsteking van skildklier
- effekte op die tiroëdfunksie, gesien in bloedtoetse verhoogde bloedcholesterol, verhoogde bloedtrigliseriede, verlaagde hoë-digtheid lipoproteïen, verlaagde lae digtheid lipoproteïen, gesien in bloedtoetse
- verhoogde bloedglukose (bloedsuiker), verhoogde bloedinsulien, toename in sommige lewerensieme ('n merker van lewerfunksie), gesien in bloedtoetse
- verhoogde of verlaagde bloedtestosteroon, verhoogde tiroëdstimulerende hormoon in die bloed, gesien in bloedtoetse
- verlaagde hemoglobien, verlaagde vlakke van witbloedselle (wat infeksie beveg) gesien in bloedtoetse
- aggressiewe gedrag, impulsiewe gedrag
- ongevoeligheid
- verwarde toestand
- depressiewe bui
- skeiding van normale geestelike prosesse (dissosiasie)
- hallusinasie (ouditief of visueel)
- moord gedagtes
- probleme om te slaap
- toename of afname in seksuele begeerte
- gebrek aan energie
- geestelike toestand verander
- obsessiewe gedagtes
- gevoel van akute en stemmende angs (paniekaanval)
- betrokke te raak in onwillekeurige bewegings wat geen doel dien nie (psigomotoriese hiperaktiwiteit)
- hiperaktiwiteit van die spiere in die liggaam (hiperkinesie), onvermoë om te rus (rusteloosheid)
- onbeheerbare drang om bene te beweeg (rustelose bene sindroom), onbeheerbare bewegings van mond, tong en ledemate (tardiewe diskinesie)
- slaapversteuring
- doelbewuste selfmoordgedagtes
- abnormale denke
- onstabiliteit (drsai sensasie)
- geheue inkorting
- abnormale veltsensasie (parestesie)
- voel asof 'n stywe band om kop is (spanningshoofpyn), migraine
- opstelike oordosering
- verandering in smaak
- diarree
- slegte spysvertering
- lip droog
- abdominale pyn of versteuring
- afwesigheid van of tekort aan afskeiding van speeksel
- tandpyn
- moeilik vir die oë om te fokus, dowwe visie
- hartdoppings, veranderinge in hartritme
- bloeddruk daal wanneer jy opstaan, wat kan veroorsaak dat jy flou word
- verhoogde bloeddruk
- borskaspyn
- elektrokardiogram veranderinge
- verhoogde sensitiwiteit van gehoor
- gedeeltelike of volledige afwesigheid van hare, abnormale haargroei
- uitslag, urtikaria
- spierspasmas en -stywheid, spierpyne
- gewrigspyne, pyn in arms en bene, pyn in kakebeen
- probleme om te loop
- teenwoordigheid van bilirubien in uriene, teenwoordigheid van proteïen in uriene, 'n merker van nierfunksie
- pyn of probleme wanneer uriene passeer, gereelde urinering, renale versteuring
- seksuele disfunksie
- probleme met ejakulasie
- abnormale borsvergroting, borspyn, melkafskeiding vanuit borste
- menstruasie afwesig of onreëlmatig
- maak onbeheerde geluide en bewegings (Tourette se versteuring)
- koue rillings
- onwelsynsgevoel
- koors

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem is nie, stel asseblief jou dokter of apteker in kennis. Sou jou algemene gesondheid versleg of indien jy enige ongunstige effekte ervaar terwyl jy **MAKTUDA** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety App (Medsafety X SAHPRA) en eReporting platform (**who-umc.org**), gevind op SAHPRA se webwerf. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **MAKTUDA** te verskaf.

5. Hoe om MAKTUDA te bewaar

Bewaar by of benede 30 °C.
HOU BUITE DIE BEREIK VAN KINDERS.
Bewaar in die oorspronklike verpakking / houer.
Hou die stulpstrook in die karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die stulpstrook / etiket / karton / bottel aangedui is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat MAKTUDA bevat
Die aktiewe bestanddeel is lurasidoonhidroliried.
Suikervry
Die ander bestanddele is:
Mannitol
Natriumkroskarmellose
Hidroksipropielmetielsellulose
Voorgelatiniseerde stysel
Magnesiumstearaat
Instacoat Universele groen en wit wat bevat:
- Hipromellose
- Polietileenglikol
- Titaandioksied
- Geel ysteroksied
- FD en C Blou No. 2 Al meer

Hoe MAKTUDA lyk en inhoud van die pak
MAKTUDA 20 mg: Wit tot naaswit, ronde bikonvekse, filmbedekte tablette, bedruk met "JP" op een kant en "20" aan die ander kant
MAKTUDA 40 mg: Wit tot naaswit, ronde bikonvekse, filmbedekte tablette, bedruk met "JP" op een kant en "40" aan die ander kant
MAKTUDA 60 mg: Wit tot naaswit, kapsuul bikonvekse, filmbedekte tablette, bedruk met "JP" op een kant en "60" aan die ander kant
MAKTUDA 80 mg: Groen tot groengeel, ovaal, bikonvekse, filmbedekte tabletle, bedruk met "JP" aan die een kant en "80" aan die ander kant
MAKTUDA 120 mg: Wit tot naaswit, ovaal, bikonvekse, filmbedekte tablette, bedruk met "JP" aan die een kant en "120" aan die ander kant

Inhoud van die pak:
Stulpstrook verpakking koue vorm:
Tablette word in 'n stulpstrook verpak wat gewone aluminiumfoelie bevat met hitteseël gelakt as die dekmateriaal en koue vorm laminaat as die vormingsmateriaal. Die stulpstrook word in 'n buitenste karton verpak.
Verpakkingsgroottes sluit 10,14, 28, 30, 56, 84, 90 en 100 in
HDPE houer:
60 cc ronde, wit, HDPE-houer met 33 mm nekafwerking, toegemaak met 'n 33 mm wit sluiting, met pulp en wit gedrukte hitteseëlvoering.
75 cc ronde, wit, HDPE-houer met 38 mm nekafwerking, toegemaak met 'n 38 mm wit sluiting, met pulp en wit gedrukte hitteseëlvoering.
Verpakkingsgrootte sluit 30, 90 in.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

7. HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1, Bassonia Estate Kantoorpark (Oos),
1 Cussonia Rylaan, Bassonia Rock, Uitbr. 12,
Alberton, Gauteng

Hierdie inligtingstuk was laas hersien in
September 2024

Registrasienommers
MAKTUDA 20 mg: 57/1.2/0772.767
MAKTUDA 40 mg: 57/1.2/0773.768
MAKTUDA 60 mg: 57/1.2/0774.769
MAKTUDA 80 mg: 57/1.2/0775.770
MAKTUDA 120 mg: 57/1.2/0776.771

Vir die ooreenstemmende Professionele inligting
Die ooreenstemmende professionele inligting kan by https://www.macleodssaproducts.co.za verkry word of deur 011 682 1169 te kontak.

MASTER COPY

1. Product: MAKTUDA 20/40/60/80/120 (Lurasidone Hydrochloride Tablet 20/40/60/80/120 mg)	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 400 (L) x 360 (W) mm
9. Design / Style: Booklet type	10. Item code No.: PM04317401
11. Artwork has been made: Actual Size	12. Pharma code No.: 34250 mini
13. Barcode/NDC No.: NA	14. Supersedes Item code No: NA
15. Revision No.: 00	16. A/W File name: Z:\LURASIDONE HYDROCHLORIDE TABLETS\01\MAKTUDA PIL - PM04317401.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
20/09/24	19/09/2024	20/09/24	04/10/24	04/10/24	05/10/24

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM04317401		

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