

ATLURA

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ATLURA 40 and 80 (Lurasidone Hydrochloride Tablets 40 mg and 80 mg)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Lurasidone is a selective blocking agent of dopamine and monoamine effects. Lurasidone does not bind to histaminergic or muscarinic receptors.

INDICATIONS: For the treatment of patients with Schizophrenia.

DOSAGE AND ADMINISTRATION: *Dosage form:* Film coated tablet, *Strength:* 40 mg and 80 mg.

CONTRAINDICATION: Hypersensitivity to the active substance, or to any of the excipients. Concomitant administration of strong CYP3A4 inhibitors (e.g. boceprevir, clarithromycin, cobicistat, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole) and strong CYP3A4 inducers (e.g. carbamazepine, phenobarbital, phenytoin, rifampicin, St John's wort (*Hypericum perforatum*)).

WARNINGS & PRECAUTIONS: *Warning: increased mortality in elderly patients with dementia related psychosis; and suicidal thoughts and behaviors.* Precautions: Parkinson's disease, high temperature and muscle stiffness, rigidity, tremors or problems moving, abnormal movements of the tongue or face, heart disease or heart disease treatment that makes you prone to low blood pressure or have a family history of irregular heartbeat, history of seizures (fits) or epilepsy, a history of blood clots, enlarged breasts in male, milky nipple discharge, absence of menstruation (amenorrhea), 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, ATLURA should not be used in children below 13 years of age.

DRUG INTERACTIONS: Medicines that also work in the brain, additive effect in a negative way with the effects of ATLURA, 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 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, 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 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). ATLURA 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.

ADVERSE REACTIONS: *Very Common:* Restlessness, Sleepiness. *Common:* Parkinsonism, Speech Problem, Dizziness, Muscle Spasms and Stiffness, Nausea, Vomiting, Rash And Itching, Indigestion,

Dry Mouth or Excess Saliva, Abdominal Pain, Difficulty Sleeping, Tiredness, Agitation and Anxiety, Weight Gain, Increase In Creatine Phosphokinase, Increase In Creatinine, *Uncommon*: Nightmares, Muscle Aches, Joint Pains, Problems Walking, Rigid Posture, Increased Blood Prolactin, Increased Blood Glucose , Increase in Some Liver Enzymes, , Increased Blood Pressure, Fainting, Fast Heartbeat, Common Cold, Hot Flush, Blurred Vision, Reduced Appetite, Sweating, Pain When Passing Urine, Tardive Dyskinesia, Tiredness and Confusion, Muscle Twitching, Hyponatremia, Lethargy, Flatulence, Neck Pain , Back Pain. *Rare*: Rhabdomyolysis, Possibly Dark Urine, Increase In Eosinophils, Angioedema. *Not Known*: Reduced Levels of White Blood Cells and Red Blood Cells, Deliberate Injury to Oneself, Sudden Feelings of Anxiety, Sleep Disorder, Spinning Sensation, Seizure (Fits), Chest Pain, Abnormal Nerve Impulses in the Heart, Slow Heart Rate, Diarrhoea , Difficulty Swallowing, Irritation to Lining of Stomach , Kidney Failure, Newborn Babies May Show The Following: Agitation, Increase or Decreases in Muscle Tone, Tremor, Sleepiness, Breathing or Feeding Problems, Abnormal Breast Enlargement, Breast Pain, Milk Secretion From Breasts, Problems with Erections, Painful or Absence of Menstrual Periods, Sudden Death associated with Heart Disease

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)