**Concomitant Use with CYP3A4 INDUCERS**

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

**BLACK BOX WARNINGS**

**INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. TABLURA Tablets are not approved for the treatment of patients with dementia-related psychosis.

**SUICIDAL THOUGHTS AND BEHAVIOURS**

In short-term studies, antidepressants increased the risk of suicidal thoughts and behaviour in children, adolescents, and young adults. In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviours.

Advise families and caregivers of the need for close observation and communication with the prescriber.

**TABLURA Tablets**

Lurasidone hydrochloride

Each film-coated tablet contains

- 40 mg
- 80 mg

**INDICATIONS**

Schizophrenia in adults ≥18 years of age

Periodic re-evaluation for long-term usefulness of the drug for the individual patient is recommended.

**DOSAGE & ADMINISTRATION**

**Starting Dose**

- 40 mg/day

**Effective Dose Range**

40 to 160 mg/day

**Maximum Dose**

160 mg/day

**DOSAGE MODIFICATIONS**

**In Special Populations**

**Kidney Impairment**

- Creatinine clearance: 30 to <50 mL/min
  - Starting dose: 20 mg/day
  - Maximum dose: 80 mg/day

- Creatinine clearance: <30 mL/min
  - Starting dose: 20 mg/day
  - Maximum dose: 40 mg/day

**Drug—Drug Interactions**

**Concomitant Use with CYP3A4 INHIBITORS**

- Lurasidone + Moderate CYP3A4 Inhibitors
  - Starting dose: 20 mg/day
  - Maximum dose: 80 mg/day

**Concomitant Use with CYP3A4 INDUCERS**

- Lurasidone + Strong CYP3A4 Inducers
  - Increase the lurasidone dose after chronic treatment (7 days or more) with the CYP3A4 inducer.

**CONTRAINDICATIONS**

- Known hypersensitivity to Lurasidone HCl or any components in the formulation
- Patients on strong CYP3A4 inhibitors
- Patients on strong CYP3A4 inducers

**PACKAGING INFORMATION**

- TABLURA Tablets 40 mg
  - Blister pack of 10 tablets

- TABLURA Tablets 80 mg
  - Blister pack of 10 tablets