Latuda® (lurasidone)
PRESCRIBING INFORMATION-SCHIZOPHRENIA
FILM-COATED TABLETS

Please refer to the full Summary of Product Characteristics (SPC) before prescribing, particularly in relation to adverse reactions, precautions and contraindications. **Presentations:** Latuda film-coated tablets, containing lurasidone hydrochloride equivalent to 18.6mg, 37.2mg and 74.5mg lurasidone. **Indication:** Latuda is indicated for the treatment of schizophrenia in adults (≥18 years). **Dosage and Administration** For oral administration: Adults: Recommended starting dose: 37mg once daily with a meal. No initial dose titration is required. Effective dose range: 37 to 148mg once daily. Dose increase should be based on physician judgement and observed clinical response. Maximum dose: 148mg per day. Elderly (≥65 years): Caution when treating with higher doses. Children and adolescents (<18 years): Not recommended, safety and efficacy not established. Dose adjustments are required in moderate and severe hepatic and renal impairment, see SPC for further details. **Contraindications:** Hypersensitivity to the active substance or any excipients. Concomitant administration of strong CYP3A4 inhibitors and inducers. **Warnings and Precautions:** Clinical improvement may take a few days to some weeks; closely monitor patient during this period. Use with caution in elderly patients with dementia who have risk factors for stroke. Not studied in elderly patients with dementia. Discontinue if patient develops signs or symptoms of neuroleptic malignant syndrome. Consider discontinuation if signs of tardive dyskinesia appear. May exacerbate underlying parkinsonism symptoms. Risk of extrapyramidal symptoms. Caution and clinical monitoring is recommended in patients with a history of seizures or conditions which potentially reduce seizure threshold, cardiovascular disorders, orthostatic hypotension, diabetes or risk factors for diabetes and weight gain. May elevate prolactin levels. All risk factors for venous thromboembolism (VTE) should be identified before and during treatment and preventative measures taken. Caution in patients with a family history of QT prolongation, hypokalaemia and concomitant medication known to prolong the QT interval. Closely supervise high risk patients for risk of suicide. Avoid grapefruit juice. **Pregnancy and lactation:** Do not use during pregnancy unless potential benefit clearly outweighs potential risk to the foetus. Breast feeding should be considered only if the potential benefit of treatment justifies the potential risk to the child. **Interactions:** Caution is advised when combining with alcohol or CNS active medications, and medicines known to cause QT prolongation; P-gp and BCRP inhibitors may increase exposure to lurasidone, lurasidone is an inhibitor of P-gp and BCRP, see SPC for details. Dose adjustment is recommended in combination with CYP3A4 inhibitors and inducers, see SPC for details. Monitoring recommended when lurasidone and CYP3A4 substrates known to have a narrow therapeutic index are coadministered. **Undesirable effects:** In clinical trials, the following adverse drug reactions were reported: very common (≥10%): akathisia, somnolence; common (≥1% to <10%): weight increased, insomnia, agitation, anxiety, restlessness, parkinsonism, dizziness, dystonia, dyskinesia, nausea, vomiting, dyspepsia, salivary hypersecretion, dry mouth, upper abdominal pain, stomach discomfort, musculoskeletal stiffness, blood creatinine phosphokinase increase, serum creatinine increase, fatigue, hypersensitivity, rash pruritus; uncommon (≥0.1% to <1%): decreased appetite, blood glucose increased, catatonia, tardive dyskinesia, tachycardia, hypertension, hypotension, alanine aminotransferase increase, blood prolactin increased, hyponatraemia; rare (≥0.01% to <0.1%): eosinophilia, rhabdomyolysis, neuroleptic malignant syndrome (NMS), angioedema. This is not a complete list of adverse reactions. Prescribers should consult the SPC in relation to all adverse reactions. **Special precautions for storage:** Store in the original package in order to protect from light. **Special precautions for disposal and other handling:** Any unused medicinal product or waste material should be disposed of in accordance with local requirements. **Legal classification:** Prescription Only Medicine (POM). **Package Quantities and Basic NHS Costs:** Latuda 18.5mg, 37mg and 74mg £90.72 per pack of 28 tablets. **Marketing Authorisation Holder:** Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F.S.p.A., Viale Amelia 70,00181, Rome, Italy. **Marketed in the UK by:** Sunovion Pharmaceuticals Europe Ltd, Southside, 97 – 105 Victoria Street, London, SW1E 6QT. Latuda is a registered trade mark. **Marketing Authorisation Number(s):** EU/1/14/913/001-021. **Date of Preparation:** November 2018 (NP-LAT-UK-00015-18).

Adverse reactions should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

Adverse reactions should also be reported to Sunovion Pharmaceuticals Europe Ltd. on 020 7821 2899