Aripiprazole 1 mg and 2.5 mg tablets – UK
Prescribing Information

Please read the Summary of Product Characteristics (SmPC) before prescribing.

PRESENTATION: 1 mg white round tablet containing 1 mg aripiprazole. 2.5 mg light grey modified rectangular tablet containing 2.5 mg aripiprazole.

INDICATIONS:
Schizophrenia. Adults and adolescents aged 15 years and older.
Adult Bipolar I Disorder. Treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in adults who have experienced predominantly manic episodes and whose manic episodes responded to aripiprazole.
Adolescent Bipolar I Disorder. Treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 and older.

POSOLOGY AND ADMINISTRATION*:* Take orally once daily without regard for meals. For higher doses, use other formulations of aripiprazole. The maximum daily dose should not exceed 30 mg. Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.
***Adult Schizophrenia*:** Recommended starting dose 10 mg/day or 15 mg/day. Maintenance dose 15 mg/day. Effective dose range 10 mg/day to 30 mg/day (enhanced efficacy at doses above 15 mg/day has not been demonstrated but individual patients may benefit from a higher dose).
Adult - Manic episodes in Bipolar I Disorder: Recommended starting dose 15 mg/day as monotherapy or combination therapy. Some patients may benefit from a higher dose.
Adult - Recurrence prevention of manic episodes in Bipolar I Disorder: For preventing recurrence of manic episodes in patients, who have been receiving aripiprazole as monotherapy or combination therapy, continue therapy at the same dose. Adjustments of daily dosage, including dose reduction should be considered based on clinical status.
Paediatric - Schizophrenia in adolescents aged 15 years and older: Recommended dose 10 mg/day. Initiate treatment at 2 mg (using aripiprazole 1 mg) for 2 days, titrated to 5 mg for 2 additional days to reach the recommended daily dose of 10 mg. When appropriate, subsequent dose increases should be administered in 5 mg increments without exceeding the maximum daily dose of 30 mg. Effective dose range 10 mg/day to 30 mg/day (enhanced efficacy above 10 mg/day has not been demonstrated but individual patients may benefit from a higher dose). Not recommended for use in patients with schizophrenia below 15 years of age due to lack of data.
Paediatric – Manic episodes in Bipolar I Disorder in adolescents aged 13 years and older: Recommended dose 10 mg/day. Initiate treatment at 2 mg (using aripiprazole 1 mg) for 2 days, titrated to 5 mg for 2 additional days to reach the recommended daily dose of 10 mg. Treatment duration should be the minimum necessary for symptom control and must not exceed 12 weeks. Enhanced efficacy at doses above 10 mg/day has not been demonstrated, and a daily dose of 30 mg is associated with a substantially higher incidence of significant adverse reactions including extrapyramidal symptoms (EPS) related events, somnolence, fatigue and weight gain. Doses higher than 10 mg/day should only be used in exceptional cases and with close clinical monitoring. Younger patients are at increased risk of experiencing adverse events associated with aripiprazole hence not recommended in patients below 13 years of age.

SPECIAL POPULATIONS: Hepatic impairment: No dose adjustment required in mild to moderate hepatic impairment. In severe hepatic impairment, data are insufficient to establish recommendations, dosing should be managed cautiously, and the maximum daily dose of 30 mg should be used with caution. Renal impairment: No dose adjustment required. Elderly (65 years and older): Safety and efficacy in the treatment of schizophrenia or manic episodes in Bipolar I Disorder has not been established. Due to the greater sensitivity of this population, consider a lower starting dose when clinical factors warrant (see warnings below). Gender and smoking status: No dose adjustment required. *Dose adjustments due to interactions:* Reduce aripiprazole dose when used concomitantly with strong CYP3A4 or CYP2D6 inhibitors. When the CYP3A4 or CYP2D6 inhibitor is withdrawn from the combination therapy, aripiprazole dose should then be increased. Increase aripiprazole dose when used concomitantly with strong CYP3A4 inducers. When the CYP3A4 inducer is withdrawn from the combination therapy, the aripiprazole dose should then be reduced to the recommended dose. See SmPC for guidance on managing these and other drug interactions.

CONTRAINDICATIONS: Hypersensitivity to the active substance or excipients (See SmPC).

WARNINGS AND PRECAUTIONS: Monitor patients closely while taking this medicine because improvement in the patient's clinical condition may take several days to some weeks. Suicidality: Suicidal behaviour has been reported early after initiation or switch of antipsychotic treatment including aripiprazole, closely supervise high risk patients. Cardiovascular (CV) disorders: Use with caution in patients with known CV disease (history of myocardial infarction or ischaemic heart disease, heart failure, or conduction abnormalities), cerebrovascular disease, conditions which predispose patients to hypotension or hypertension, including accelerated or malignant. Identify all possible risk factors for venous thromboembolism (VTE) before and during treatment with aripiprazole and take preventive measures. QT prolongation: Use with caution in patients with a family history of QT prolongation. Tardive dyskinesia: Consider a dose reduction or discontinuation if signs and symptoms of tardive dyskinesia appear in a patient on aripiprazole. These symptoms can temporally deteriorate or can even arise after treatment discontinuation. Other extrapyramidal symptoms (EPS): In paediatric clinical trials akathisia and Parkinsonism were observed. Consider dose reduction and close clinical monitoring if signs and symptoms of other EPS appear. Neuroleptic Malignant Syndrome (NMS): NMS is a potentially fatal symptom complex associated with antipsychotics with rare cases reported during clinical trials. If a patient develops signs and symptoms indicative of NMS or presents with unexplained high fever without additional clinical manifestations of NMS, all antipsychotics, including aripiprazole must be discontinued. Seizure: Uncommon cases reported in clinical trials. Use with caution in patients with a history of seizure disorder or who have conditions associated with seizures. **Elderly patients with dementia-related psychosis***: Increased mortality and Cerebrovascular adverse reactions:* Causes of deaths were varied, however most deaths appeared to be either CV (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. Cerebrovascular adverse reactions (e.g., stroke, transient ischaemic attack), including fatalities, have been reported and a significant dose response relationship for cerebrovascular adverse reactions in patients treated with aripiprazole was observed. Aripiprazole is not indicated for the treatment of patients with dementia-related psychosis. Hyperglycaemia and diabetes mellitus: Hyperglycaemia, in some cases extreme and associated with ketoacidosis or hyperosmolar coma or death, has been reported in patients treated with atypical antipsychotics, including aripiprazole. Risk factors that may predispose to severe complications include obesity and family history of diabetes. Patients treated with any antipsychotics, including aripiprazole, should be observed for signs and symptoms of hyperglycaemia (such as polydipsia, polyuria, polyphagia and weakness) and patients with diabetes mellitus or with risk factors for

diabetes mellitus should be monitored regularly for worsening of glucose control. Hypersensitivity: Hypersensitivity reactions, characterised by allergic symptoms, may occur with aripiprazole. Weight gain: There have been post marketing reports of weight gain usually in those with significant risk factors such as history of diabetes, thyroid disorder or pituitary adenoma. In clinical trials in adults aripiprazole has not been shown to induce clinically relevant weight gain. In clinical trials of adolescent patients with bipolar mania, aripiprazole has been shown to be associated with weight gain after 4 weeks of treatment. Monitor weight in adolescent patients with bipolar mania and consider dose reduction if weight gain is clinically significant. Dysphagia: Oesophageal dysmotility and aspiration have been associated with the use of antipsychotics, including aripiprazole. Use cautiously in patients at risk for aspiration pneumonia. Pathological gambling and other impulse control disorders: Ask patients or their caregivers specifically about the development of new or increased gambling urges, sexual urges, compulsive shopping, binge or compulsive eating, or other urges while being treated with aripiprazole. Impulse-control symptoms can be associated with the underlying disorder; however, in some cases, urges were reported to have stopped when the dose was reduced, or the medication was discontinued. Impulse control disorders may result in harm to the patient and others if not recognised. Consider dose reduction or stopping the medication if a patient develops such urges while taking aripiprazole. Lactose: Aripiprazole tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. Patients with attention deficit hyperactivity disorder (ADHD) comorbidity: Very limited safety data available on concomitant use of aripiprazole and stimulants; therefore, extreme caution should be taken when these medicinal products are co-administered. Falls: Aripiprazole may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls. Caution when treating patients at higher risk, and a lower starting dose should be considered (e.g., elderly or debilitated patients; see SmPC).

FERTILITY, PREGNANCY AND LACTATION: Fertility: Aripiprazole did not impair fertility based on data from reproductive toxicity studies. Pregnancy: Do not use in pregnancy unless the expected benefit clearly justifies the potential risk to the foetus. Congenital anomalies have been reported; animal studies could not exclude potential developmental toxicity. Advise patients to notify their physician if they become pregnant or intend to become pregnant during treatment with aripiprazole. Newborn infants exposed to antipsychotics (including aripiprazole) during the third trimester of pregnancy are at risk of adverse reactions including extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder. Consequently, newborn infants should be monitored carefully. Lactation: Aripiprazole/metabolites are excreted in human milk. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from aripiprazole therapy considering the benefit of breast-feeding for the child and the benefit of therapy for the woman.

DRIVING AND USING MACHINES: Aripiprazole has minor to moderate influence on the ability to drive and use machines due to potential nervous system and visual effects.

UNDESIRABLE EFFECTS: Based on adverse events reported during clinical trials and/or post-marketing use. *Common (≥ 1/100 to < 1/10)*: diabetes mellitus, insomnia, anxiety, restlessness, akathisia, extrapyramidal disorder, tremor, headache, sedation, somnolence, dizziness, vision blurred, constipation, dyspepsia, nausea, salivary hypersecretion, vomiting, fatigue. Adolescents aged 13 years and older experienced side effects that were similar in frequency and type to those in adults except that somnolence/sedation, akathisia, EPS disorder and fatigue were *very common (≥ 1/10)* and upper abdominal pain, dry mouth, increased heart rate, increased weight, decreased weight, increased appetite, muscle twitching, dyskinesia, orthostatic hypotension, blood insulin increased, arrhythmia and leukopenia were *common (≥ 1/100 to < 1/10)*.
Serious adverse events: *Common (≥ 1/100 to < 1/10);* Diabetes mellitus, extrapyramidal disorder. *Uncommon (≥ 1/1000 to < 1/100);* Hyperprolactinaemia, hyperglycaemia, depression, tardive dyskinesia, dystonia, diplopia, tachycardia, *Not known*: Leukopenia, neutropenia, thrombocytopenia, allergic reaction (e.g. anaphylactic reaction, angioedema including swollen tongue, tongue oedema, face oedema, allergic pruritis or urticaria), diabetic hyperosmolar coma, diabetic ketoacidosis, hyponatremia, anorexia, suicide attempt, suicidal ideation and completed suicide, neuroleptic malignant syndrome, grand mal convulsion, serotonin syndrome, oculogyric crisis, sudden death unexplained, torsades de pointes, ventricular arrhythmia, cardiac arrest, bradycardia, heart failure, stroke, transient ischaemic attack, venous thromboembolism (including pulmonary embolism and deep vein thrombosis), hypertension, syncope, aspiration pneumonia, infections (e.g. pneumonia), pancreatitis, dysphagia, hepatic failure, hepatitis, jaundice, drug reactions with eosinophilia and systemic symptoms (DRESS), rhabdomyolosis, urinary retention, drug withdrawal syndrome neonatal, priapism, temperature regulation disorder (e.g. hypothermia, pyrexia), QT prolonged. **Refer to SmPC for other side effects.**

LEGAL CATEGORY: POM
PRESENTATIONS, BASIC NHS COSTS AND MARKETING AUTHORISATION (MA) NUMBER:
Aripiprazole 1 mg (PL 00111/0216), 28 tablet pack £29.50.
Aripiprazole 2.5 mg (PL 00111/0217), 28 tablet pack tablet £29.50.
MA HOLDER: DHP Healthcare Limited (trading as Wyntra Pharmaceuticals), 13 Hanover Square, London, W1S 1HN, UK

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/. Adverse events should also be reported to Wyntra by emailing medinfo@wyntra.com or calling 0330 1359 454

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