ABILIFY® (aripiprazole) PRESCRIBING INFORMATION

See Summary of Product Characteristics before prescribing.

PRESENTATION: Tablets: 5mg, 10mg, 15mg, 30mg aripiprazole; orodispersible tablets (ODT): 10mg, 15mg aripiprazole; oral solution OS): 1mg/ml aripiprazole; solution for injection for intramuscular use (IM): 7.5mg/ml aripiprazole (1.3ml vial containing 9.75mg aripiprazole).

INDICATIONS: Oral formulations: Adults: Schizophrenia: Moderate to severe manic episodes in bipolar I Disorder & prevention of new manic episodes in aripiprazole respondent patients; Paediatric patients: Schizophrenia in adolescents 15 years and older.

IM: Rapid control of agitation & disturbed behaviours in schizophrenia or manic episodes in bipolar I Disorder.

DOSEAGE: Oral formulations: Adults: Schizophrenia: Usual starting dose is 10 or 15mg once daily with or without food. Effective dose range is 10 to 30mg with a recommended maintenance dose of 15mg. Mania in Bipolar I Disorder: Usual starting dose is 15mg once daily with or without food as monotherapy or combination therapy. For recurrence prevention, continue at same dose. Dose adjustment on basis of clinical status. Paediatric patients: Schizophrenia: Recommended dose is 10mg/day once daily with or without food. Treatment to be initiated at 2 mg (using ABILIFY Oral Solution 1 mg/ml) for two days, titrated to 5 mg for two more days to reach recommended daily dose of 10 mg. Effective dose range is 10 to 30 mg/day.

IM: Initial dose 9.75mg (1.3ml) injection. Effective dose range: 5.25 to 15mg as single injection. Lower dose of 5.25 mg (0.7 ml) may be given. Second injection may be administered two hours after the first, on basis of individual clinical status. No more than three injections in any 24-hour period.

For all formulations (adult and paediatric patients): Maximum daily dose 30mg. No dosage adjustment required in renal or mild to moderate hepatic impairment. Elderly (>65 years): Efficacy not established. Consider lower starting dose. Not recommended for use in patients below 15 years of age. Safety and efficacy not established.

CONTRAINDICATIONS: Hypersensitivity to any ingredient.

WARNINGS AND PRECAUTIONS: Clinical improvement may take several days to some weeks: monitor patient throughout this period. Reduce dose or discontinue if signs of tardive dyskinesia appear. Discontinue if patient develops signs and symptoms indicative of neuroleptic malignant syndrome. Caution in patients with a history of seizure, cardiovascular disorders, conduction abnormalities, diabetes and elderly patients with dementia-related psychosis and those at risk of aspiration pneumonia (see SPC). All risk factors for venous thromboembolism (VTE) should be identified before and during treatment with ABILIFY and preventive measures taken. Do not use in pregnancy unless benefit outweighs risk (see SPC); breastfeeding not advised. Until individual patient response established, caution not to drive or operate machinery.

IM: observe patients for orthostatic hypotension and regularly monitor blood pressure, pulse, respiratory rate and level of consciousness. If additional parenteral benzodiazepine therapy is deemed necessary, monitor patients for excessive sedation and for orthostatic hypotension.

DRUG INTERACTIONS: Increased hypotensive effect with certain antihypertensives. Caution is advised when combining with alcohol or other CNS medication with overlapping side effects such as sedation; also with certain antifungals, antibacterial drugs, antivirals, anticoagulants, St John's Wort and medicines known to QT prolongation or electrolyte imbalance. Reduce aripiprazole dose with concomitant use of potent CYP3A4 or CYP2D6 inhibitors, e.g. fluoxetine, paroxetine. Increase aripiprazole dose with concomitant use of potent CYP3A4 inducers, e.g. carbamazepine. See SPC. IM: increased sedation when combined with lorazepam.

UNEXPECTED EFFECTS: The following adverse drug reactions were reported: Tablets, ODT, OS, IM common (≥1/100 <1/10): somnolence, dizziness, headache, akathisia, nausea, vomiting; Tablets, ODT, OS common: restlessness, insomnia, anxiety, extrapyramidal disorder, tremor, sedation, blurred vision, dyspepsia, constipation, salivary hypersecretion, fatigue; Tablets, ODT, OS, IM: uncommon (≥1/1000 <1/100): tachycardia, orthostatic hypotension; IM uncommon (≥1/1000 <1/100): increased diastolic blood pressure, fatigue, dry mouth; Tablets, ODT, OS uncommon (≥1/1000 <1/100): depression. In adolescent (13-17 years) placebo-controlled trials, the adverse drug reactions reported were similar to those for adults; the following adverse drug reactions were reported more frequently than for adults: very common (≥1/10): somnolence, sedation, extrapyramidal disorder; common (≥1/100 <1/10): dry mouth, increased appetite, orthostatic hypotension. Other adverse events from post-marketing surveillance include; allergic reaction (anaphylaxis & angioedema), pancreatitis, priapism, suicide, rhabdomyolysis, hyperglycaemia, diabetes, dysphagia, convulsions, cardiac disorders including arrhythmias & sudden unexplained death, VTE (including pulmonary embolism and deep vein thrombosis), hypertension, hepatitis, leukopenia and thrombocytopenia, drug withdrawal syndrome neonatal. Symptoms of dystonia may occur in susceptible individuals during the first few days of treatment, with an elevated risk of acute dystonia observed in males and younger age groups. Other findings see SPC.

OVERDOSAGE: Treatment should be symptomatic and supportive: adequate airway maintenance, cardiovascular monitoring and close medical supervision. Activated charcoal reduces serum concentrations.

LEGAL CATEGORY: POM

AUTHORISATION NUMBERS & BASIC NHS PRICE: 28 tablets; 5mg (EU/1/04/276/002) £96.04, 10mg (EU/1/04/276/007) £96.04, 15mg (EU/1/04/276/012) £96.04, 30mg (EU/1/04/276/017) £192.08. 28 orodispersible tablets; 10mg (EU/1/04/276/025) £96.04, 15mg (EU/1/04/276/028) £96.04. 150mL bottle 1mg/ml oral solution: (EU/1/04/276/034) £102.90. 1.3ml vial 7.5mg/ml solution for injection: (EU/1/04/276/036) £3.43.

MARKETING AUTHORISATION HOLDER: Otsuka Pharmaceutical Europe Ltd, Hunton House, Highbridge Business Park, Oxford Road, Uxbridge, Middlesex UB8 1HU

FURTHER INFORMATION FROM: Bristol-Myers Squibb Pharmaceuticals Ltd., Uxbridge Business Park, Sanderson Road, Uxbridge, Middlesex, UB8 1DH. Tel: 0800-731-1736

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Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Bristol-Myers Squibb Pharmaceuticals Ltd Medical Information on 0800 731 1736 or medical.information@bms.com.