Summary of prescribing information for ASPRITO tablets

Active Ingredient: ASPRITO tablets contain aripiprazole 5 mg, 10 mg, 15 mg, 20 mg & 30 mg. **Indication:** treatment of schizophrenia. **Dosage:** Tablets should be administered once daily without regard to meals. Initial Dose: 10-15 mg/day, Recommended dose: 10-15 mg/day; Maximum Dose: 30 mg/day. **Contraindications:** Known hypersensitivity to aripiprazole. **Warning and precautions:** Elderly patients with dementia-related psychosis: increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack, including fatalities. Suicidality and antidepressants: increased risk of suicidality in children, adolescents, and young adults with major depressive disorder. Neuroleptic Malignant Syndrome: manage with immediate discontinuation and close monitoring. Tardive dyskinesia: discontinue if clinically appropriate. Hyperglycemia and diabetes mellitus: monitor glucose regularly in patients with and at risk for diabetes. Pathological Gambling and Other Compulsive Behaviors: Consider dose reduction or discontinuation. Orthostatic hypotension: use with caution in patients with known cardiovascular or cerebrovascular disease. Leukopenia, neutropenia, and agranulocytosis: have been reported with antipsychotics including aripiprazole. Seizures/convulsions: use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. Potential for cognitive and motor impairment: use caution when operating machinery. Suicide: the possibility of a suicide attempt is inherent in schizophrenia and bipolar disorder. Closely supervise high-risk patients. **Pregnancy & Lactation:** Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure. Limited data from published literature report the presence of aripiprazole in human breast milk. There are reports of poor weight gain in breastfed infants exposed to aripiprazole and reports of inadequate milk supply in lactating women taking aripiprazole. **Interaction:** Known CYP2D6 Poor Metabolizers: Administer half of usual dose. Known CYP2D6 Poor Metabolizers and strong CYP3A4 inhibitors: Administer a quarter of usual dose. Strong CYP2D6 or CYP3A4 inhibitors: Administer half of usual dose. Strong CYP2D6 and CYP3A4 inhibitors: Administer a quarter of usual dose. Strong CYP3A4 inducers: Double usual dose over 1 to 2 weeks. **Adverse reactions:** most common nausea, vomiting, constipation, headache, dizziness, akathisia, anxiety, insomnia, and restlessness. **Overdose:** Symptoms include vomiting, somnolence, and tremor. Other clinically important signs and symptoms observed in one or more patients with aripiprazole overdoses (alone or with other substances) include acidosis, aggression, aspartate aminotransferase increased, atrial fibrillation, bradycardia, coma, confusional state, convulsion, blood creatine phosphokinase increased, depressed level of consciousness, hypertension, hypokalemia, hypotension, lethargy, loss of consciousness, QRS complex prolonged, QT prolonged, pneumonia aspiration, respiratory arrest, status epilepticus, and tachycardia. Management: No specific information is available. An electrocardiogram should be obtained in case of overdosage and if QT interval prolongation is present, cardiac monitoring should be instituted. Management should concentrate on supportive therapy, maintaining an adequate airway, oxygenation and ventilation, and management of symptoms. Close medical supervision and monitoring should continue until the patient recovers. Charcoal: an early charcoal administration may be useful in partially preventing the absorption of aripiprazole. Administration of 50 g of activated charcoal, one hour after a single 15 mg oral dose of aripiprazole, decreased the mean AUC and Cmax of aripiprazole by 50%. Hemodialysis: there is no information on the effect of hemodialysis. However, hemodialysis is unlikely to be useful in overdose management since aripiprazole is highly bound to plasma proteins.

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It is recommended to refer full prescribing information before prescription.

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