xxxxxxx-5233

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

ARIPTOR TABLET 5 MG
ARIPTOR TABLET 10 MG
ARIPTOR TABLET 15 MG
ARIPTOR TABLET 20 MG

Aripiprazole Tablets U.S.P. 5mg/10mg/15mg/20mg

BRAND OR PRODUCT NAME

ARIPTOR TABLET 5 MG / ARIPTOR TABLET 10 MG / ARIPTOR TABLET 15 MG / ARIPTOR TABLET 20 MG

NAME AND STRENGTH OF ACTIVE SUBSTANCE(S)

ARIPTOR TABLET 5 MG
Each uncoated tablet contains:
Aripiprazole U.S.P. 5 mg
Excipients q.s.
ARIPTOR TABLET 10 MG
Each uncoated tablet contains:
Aripiprazole U.S.P. 10 mg
Excipients q.s.
ARIPTOR TABLET 15 MG
Each uncoated tablet contains:
Aripiprazole U.S.P. 15 mg
Excipients q.s.
ARIPTOR TABLET 20 MG
Each uncoated tablet contains:
Aripiprazole U.S.P. 20 mg
Excipients q.s.

PRODUCT DESCRIPTION

ARIPTOR TABLET 5 MG
White to off-white, round uncoated tablets debossed with "5" on one side and "17" on other side.
ARIPTOR TABLETS 10 MG
White to off-white, round uncoated tablets debossed with "10" on one side and "18" on the other side.
ARIPTOR TABLETS 15 MG
White to off-white, round uncoated tablets debossed with "15" on one side and "19" on the other side.
ARIPTOR TABLET 20 MG
White to off-white, round uncoated tablets debossed with "20" on both sides.

DOSAGE FORM

Uncoated tablets

CLINICAL PARTICULARS

Therapeutics indications

Aripiprazole is indicated for the treatment of acute episodes of schizophrenia and for maintenance of clinical improvement.
Aripiprazole is indicated for the treatment of acute manic episodes associated with Bipolar I Disorder.

Posology and Method of Administration

Posology Adults
Schizophrenia
The recommended starting dose for Aripiprazole is 10 or 15 mg/day with a maintenance dose of 15 mg/day administered on a once-a-day schedule without regard to meals. Aripiprazole is effective in a dose range of 10 to 30 mg/day. Enhanced efficacy at doses higher than a daily dose of 15 mg has not been demonstrated although individual patients may benefit from a higher dose. The maximum daily dose should not exceed 30 mg.
Manic episodes in Bipolar I Disorder
The recommended starting dose for Aripiprazole is 15 mg administered on a once-a-day schedule. Some patients may benefit from a higher dose. The maximum daily dose should not exceed 30 mg.
Hepatic impairment
No dosage adjustment is required for patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the data available are insufficient to establish recommendations. In these patients dosing should be managed cautiously. However, the maximum daily dose of 30 mg should be used with caution in patients with severe hepatic impairment.
Renal impairment
No dosage adjustment is required in patients with renal impairment.
Elderly
The effectiveness of Aripiprazole in the treatment of schizophrenia and Bipolar I Disorder in patients aged 65 years and older has not been established. Owing to the greater sensitivity of this population, a lower starting dose should be considered when clinical factors warrant.
Gender
No dosage adjustment is required for female patients as compared to male patients.
Smoking Status
According to the metabolic pathway of aripiprazole no dosage adjustment is required for smokers.
Dose adjustments due to interactions
When concomitant administration of potent CYP3A4 or CYP2D6 inhibitors with aripiprazole occurs, the aripiprazole dose should be reduced. When the CYP3A4 or CYP2D6 inhibitor is withdrawn from the combination therapy, aripiprazole dose should then be increased.
When concomitant administration of potent CYP3A4 inducers with aripiprazole occurs, the aripiprazole dose should be increased. When the CYP3A4 inducer is withdrawn from the combination therapy, the aripiprazole dose should then be reduced to the recommended dose.
Mode of administration
Ariptor tablet is for oral use.

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed.

Special warnings and precautions for use

During antipsychotic treatment, improvement in the patient's clinical condition may take several days to some weeks. Patients should be closely monitored throughout this period.
Suicidality
The occurrence of suicidal behaviors is inherent in psychotic illnesses and mood disorders and in some cases has been reported early after initiation or switch of antipsychotic therapy, including treatment with aripiprazole. Close supervision of high-risk patients should accompany antipsychotic therapy.
Cardiovascular disorders
Aripiprazole should be used with caution in patients with known cardiovascular disease (history of myocardial infarction or ischaemic heart disease, heart failure, or conduction abnormalities), cerebrovascular disease, conditions which would predispose patients to hypotension (dehydration, hypovolemia, and treatment with antihypertensive medicinal products) or hypertension, including accelerated or malignant. Cases of venous thromboembolism (VTE) have been reported with antipsychotic medicinal products. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all possible risk factors for VTE should be identified before and during treatment with aripiprazole and preventive measures undertaken.
QT prolongation
As with other antipsychotics, aripiprazole should be used with caution in patients with a family history of QT prolongation.
Tardive dyskinesia
If signs and symptoms of tardive dyskinesia appear in a patient on aripiprazole, dose reduction or discontinuation should be considered.
Other extrapyramidal symptoms
If signs and symptoms of other EPS appear in a patient taking aripiprazole, dose reduction and close clinical monitoring should be considered.
Neuroleptic Malignant Syndrome (NMS)
NMS is a potentially fatal symptom complex associated with antipsychotic medicinal products. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmia). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. However, elevated creatine phosphokinase and rhabdomyolysis, not necessarily in association with NMS, have also been reported. If a patient develops signs and symptoms indicative of NMS or presents with unexplained high fever without additional clinical manifestations of NMS, all antipsychotic active substances, including aripiprazole, must be discontinued.
Seizure
Uncommon cases of seizure were reported during treatment with aripiprazole. Therefore, aripiprazole should be used with caution in patients who have a history of seizure disorder or have conditions associated with seizures.
Elderly patients with dementia-related psychosis
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Aripiprazole is not indicated for the treatment of 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. Assessment of the relationship between atypical antipsychotics use and glucose abnormalities is complicated by the possibility of an increased background risk of diabetes mellitus in patients with schizophrenia and the increasing incidence of diabetes mellitus in the general population. Given these confounders, the relationship between atypical antipsychotic use and hyperglycemia-related adverse events is not completely understood. However, epidemiological studies suggest an increased risk of treatment- emergent hyperglycaemia-related adverse events in the patients treated with the atypical antipsychotics. Precise risk estimates for hyperglycaemia-related adverse events in patients treated with atypical antipsychotics are not available.
Patients with an established diagnosis of diabetes mellitus who are started on atypical antipsychotics should be monitored regularly for worsening of glucose control. Patients with risk factors for diabetes mellitus (e.g. obesity, family history of diabetes) who are starting treatment with atypical antipsychotics should undergo fasting blood glucose testing at the beginning of treatment and periodically during treatment. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycaemia during treatment with atypical antipsychotics should undergo fasting blood glucose testing. In some cases, hyperglycaemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation of anti-diabetic treatment despite discontinuation of the suspect drug.
Hypersensitivity
As with other medicinal products, hypersensitivity reactions, characterised by allergic symptoms, may occur with aripiprazole.
Weight gain
Weight gain is commonly seen in schizophrenic and bipolar mania patients due to co-morbidities, use of antipsychotics known to cause weight gain, poorly managed lifestyle, and might lead to severe complications.
Dysphagia
Oesophageal dysmotility and aspiration have been associated with antipsychotic medicinal product use, including aripiprazole. Aripiprazole and other antipsychotic active substances should be used cautiously in patients at risk for aspiration pneumonia.
Pathological gambling and impulse-control problems
Patients can experience increased urges, particularly for gambling, and the inability to control these urges while taking aripiprazole. Other urges reported include: increased sexual urges, compulsive shopping, binge or compulsive eating, and other impulsive and compulsive behaviours.
It is important for prescribers to ask patients or their caregivers specifically about the development of new or increased gambling urges, or other urges, while being treated with aripiprazole. It should be noted that 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. Patients who are at higher risk for impulse-control problems (e.g. personal or family history of obsessive-compulsive disorder, impulse-control disorder, bipolar disorder, impulsive personality, alcoholism, drug abuse or other addictive behaviours) would require closer monitoring for new or worsening of uncontrollable urges. Impulse-control problems may result in harm to the patient and others if not recognized. Consider dose reduction or stopping the medication if a patient develops such urges while taking aripiprazole.

Interaction with Other Medicinal Products and Other Forms of Interaction

Due to its α1-adrenergic receptor antagonism, aripiprazole has the potential to enhance the effect of certain antihypertensive agents.
Given the primary CNS effects of aripiprazole, caution should be used when aripiprazole is taken in combination with alcohol or other CNS medicinal products with overlapping adverse reactions such as sedation.
If aripiprazole is administered concomitantly with medicinal products known to cause QT prolongation or electrolyte imbalance, caution should be used.
Potential for other medicinal products to affect aripiprazole
A gastric acid blocker, the H2 antagonist famotidine, reduces aripiprazole rate of absorption but this effect is deemed not clinically relevant. Aripiprazole is metabolized by multiple pathways involving the CYP2D6 and CYP3A4 enzymes but not CYP1A enzymes. Thus, no dosage adjustment is required for smokers.
Quinidine and other CYP2D6 inhibitors
Potent inhibitor of CYP2D6 (quinidine) increased aripiprazole AUC by 107%, while Cmax was unchanged. The AUC and Cmax of dehydro-aripiprazole, the active metabolite, decreased by 32% and 47%, respectively. Aripiprazole dose should be reduced to approximately one-half of its prescribed dose when concomitant administration of aripiprazole with quinidine occurs. Other potent inhibitors of CYP2D6, such as fluoxetine and paroxetine, may be expected to have similar effects and similar dose reductions should therefore be applied.
Ketoconazole and other CYP3A4 inhibitors
Potent inhibitor of CYP3A4 (ketoconazole) increased aripiprazole AUC and Cmax by 63% and 37%, respectively. The AUC and Cmax of dehydro-aripiprazole increased by 77% and 43%, respectively. In CYP2D6 poor metabolisers, concomitant use of potent inhibitors of CYP3A4 may result in higher plasma concentrations of aripiprazole compared to that in CYP2D6 extensive metabolizers.
When considering concomitant administration of ketoconazole or other potent CYP3A4 inhibitors with aripiprazole, potential benefits should outweigh the potential risks to the patient. When concomitant administration of ketoconozole with aripiprazole occurs, aripiprazole dose should be reduced to approximately one-half of its prescribed dose. Other potent inhibitors of CYP3A4, such as itraconazole and HIV protease inhibitors, may be expected to have similar effects and similar dose reductions should therefore be applied.
Upon discontinuation of the CYP2D6 or CYP3A4 inhibitor, the dosage of aripiprazole should be increased to the level prior to the initiation of the concomitant therapy.
When weak inhibitors of CYP3A4 (e.g., diltiazem or escitalopram) or CYP2D6 are used concomitantly with aripiprazole, modest increases in aripiprazole concentrations might be expected.
Carbamazepine and other CYP3A4 inducers
Following concomitant administration of carbamazepine, a potent inducer of CYP3A4, the geometric means of Cmax and AUC for aripiprazole were 68% and 73% lower, respectively, compared to when aripiprazole (30 mg) was administered alone. Similarly, for dehydro- aripiprazole the geometric means of Cmax and AUC after carbamazepine co-administration were 69% and 71% lower, respectively, than those following treatment with aripiprazole alone.
Aripiprazole dose should be doubled when concomitant administration of aripiprazole occurs with carbamazepine. Other potent inducers of CYP3A4 (such as rifampicin, rifabutin, phenytoin, phenobarbital, primidone, efavirenz, nevirapine and St. John's Wort) may be expected to have similar effects and similar dose increases should therefore be applied. Upon discontinuation of potent CYP3A4 inducers, the dosage of aripiprazole should be reduced to the recommended dose.
Valproate and lithium
When either valproate or lithium was administered concomitantly with aripiprazole, there was no clinically significant change in aripiprazole concentrations.
Potential for aripiprazole to affect other medicinal products
When aripiprazole was administered concomitantly with either valproate, lithium or lamotrigine, there was no clinically important change in valproate, lithium, or lamotrigine concentrations.
Serotonin syndrome
Cases of serotonin syndrome have been reported in patients taking aripiprazole, and possible signs and symptoms for this condition can occur especially in cases of concomitant use with other serotonergic drugs, such as SSRI/SNRI, or with medicinal products that are known to increase aripiprazole concentrations.

Fertility, Pregnancy and Lactation

Patients should be advised to notify their doctors if they become pregnant or intend to become pregnant during therapy with Aripiprazole.
Neonates exposed to antipsychotic drugs including Aripiprazole during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalization.
Ariptor should be used during pregnancy only if the potential benefits justify the potential risk to the foetus.
Breast-feeding
Aripiprazole is excreted in human breast milk. Patients should be advised not to breast feed if they are taking aripiprazole.

Effects on Ability to Drive and Use Machines

Aripiprazole has minor to moderate influence on the ability to drive and use machines due to potential nervous system and visual effects, such as sedation, somnolence, syncope, vision blurred, diplopia.

Undesirable Effects

Summary of the safety profile
Undesirable effects known to be associated with antipsychotic therapy and also reported during treatment with aripiprazole. All ADRs are listed by system organ and frequency; common, uncommon and not known.
Tabulated list of adverse reactions

	Common	Uncommon	Not known
Blood and lymphatic system disorders			Leukopenia Neutropenia Thrombocytopenia
Immune system disorders			Allergic reaction (e.g. anaphylactic reaction, angioedema including swollen tongue, tongue oedema, face oedema, pruritus, or urticaria)
Endocrine disorders		Hyperprolactinaemia	Diabetic hyperosmolar coma Diabetic ketoacidosis Hyperglycaemia
Metabolism and nutrition disorders	Diabetes mellitus	Hyperglycaemia	Hyponatremia Anorexia Weight decreased Weight gain
Psychiatric disorders	Insomnia Anxiety Restlessness	Depression, Hypersexuality	Suicide attempt, suicidal ideation and completed suicide Pathological gambling Aggression Agitation Nervousness
Nervous system disorders	Akathisia Extrapyramidal disorder Tremor Headache Sedation Somnolence Dizziness	Tardive dyskinesia Dystonia	Neuroleptic Malignant Syndrome (NMS) Grand mal convulsion Serotonin syndrome Speech disorder
Eye disorders	Vision blurred	Diplopia	
Cardiac disorders		Tachycardia	Sudden unexplained death Torsades de pointes QT prolongation Ventricular arrhythmias Cardiac arrest Bradycardia
Vascular disorders		Orthostatic hypotension	Venous thromboembolism (including pulmonary embolism and deep vein thrombosis) Hypertension Syncope
Respiratory, thoracic and mediastinal disorders		Hiccups	Aspiration pneumonia Laryngospasm Oropharyngeal spasm
Gastrointestinal disorders	Constipation Dyspepsia Nausea Salivary hypersecretion Vomiting		Pancreatitis Dysphagia Diarrhoea Abdominal discomfort Stomach discomfort
Hepatobiliary disorders			Hepatic failure Hepatitis Jaundice Increased Alanine Aminotransferase (ALT) Increased Aspartate Aminotransferase (AST) Increased Gamma Glutamyl Transferase (GGT) Increased alkaline phosphatase
Skin and subcutaneous tissue disorders			Rash Photosensitivity reaction Alopecia Hyperhidrosis
Musculoskeletal and connective tissue disorders			Rhabdomyolysis Myalgia Stiffness
Renal and urinary disorders			Urinary incontinence Urinary retention
Pregnancy, puerperium and perinatal conditions			Drug withdrawal syndrome neonatal
Reproductive system and breast disorders			Priapism
General disorders and administration site conditions	Fatigue		Temperature regulation disorder (e.g. hypothermia, pyrexia) Chest pain Peripheral oedema
Investigations			Blood glucose increased Glycosylated haemoglobin increased Blood glucose fluctuation Increased creatine phosphokinase

Dystonia
Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. While these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and at higher doses of first generation antipsychotic medicinal products. An elevated risk of acute dystonia is observed in males and younger age groups.
Psychiatric disorders
Pathological gambling, hypersexuality, impulse-control problems (See Section Warnings and Precautions).
Nervous System Disorder
Restless legs syndrome
Respiratory, Thoracic and Mediastinal Disorder
Sleep apnoea. Atypical antipsychotic drugs, such as Aripiprazole, have been associated with cases of sleep apnoea, with or without concomitant weight gain. In patients who have a history of or are at risk for sleep apnoea, Ariptor should be prescribed with caution.
Prolactin
Both increase and decrease in serum prolactin as compared to baseline was observed with aripiprazole.

Overdose

Signs and symptoms
The potentially medically important signs and symptoms observed included lethargy, increased blood pressure, somnolence, tachycardia, nausea, vomiting and diarrhoea.
In addition, reports of accidental overdose with aripiprazole alone (up to 195 mg) in children have been received with no fatalities. The potentially medically serious signs and symptoms reported included somnolence, transient loss of consciousness and extrapyramidal symptoms.
Management of overdose
Management of overdose should concentrate on supportive therapy, maintaining an adequate airway, oxygenation and ventilation, and management of symptoms. The possibility of multiple medicinal product involvement should be considered. Therefore, cardiovascular monitoring should be started immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias. Following any confirmed or suspected overdose with aripiprazole, close medical supervision and monitoring should continue until the patient recovers.
Activated charcoal (50 g), administered one hour after aripiprazole, decreased aripiprazole Cmax by about 41% and AUC by about 51%, suggesting that charcoal may be effective in the treatment of overdose.
Haemodialysis
There is no information on the effect of haemodialysis in treating an overdose with aripiprazole, haemodialysis is unlikely to be useful in overdose management since aripiprazole is highly bound to plasma proteins.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Pharmacotherapeutic group: other antipsychotics, ATC code: N05AX12
Mechanism of action
It has been proposed that aripiprazole's efficacy in schizophrenia and Bipolar I Disorder is mediated through a combination of partial agonism at dopamine D_2 and serotonin $5HT_{1a}$ receptors and antagonism of serotonin $5HT_{2a}$ receptors. Aripiprazole exhibited antagonist properties in animal models of dopaminergic hyperactivity and agonist properties in animal models of dopaminergic hypoactivity. Aripiprazole exhibited high binding affinity *in vitro* for dopamine D_2 and D_3, serotonin $5HT_{1a}$ and $5HT_{2a}$ receptors and moderate affinity for dopamine D_4, serotonin $5HT_{2c}$ and $5HT_7$, alpha- 1 adrenergic and histamine H_1 receptors. Aripiprazole also exhibited moderate binding affinity for the serotonin reuptake site and no appreciable affinity for muscarinic receptors. Interaction with receptors other than dopamine and serotonin subtypes may explain some of the other clinical effects of aripiprazole.
Aripiprazole doses ranging from 0.5 to 30 mg administered once a day to healthy subjects for 2 weeks produced a dose-dependent reduction in the binding of ^{11}C-raclopride, a D_2/D_3 receptor ligand, to the caudate and putamen detected by positron emission tomography.

Pharmacokinetic properties

Absorption
Aripiprazole is well absorbed, with peak plasma concentrations occurring within 3-5 hours after dosing. Aripiprazole undergoes minimal pre-systemic metabolism. The absolute oral bioavailability of the tablet formulation is 87 %. There is no effect of a high fat meal on the pharmacokinetics of aripiprazole.
Distribution
Aripiprazole is widely distributed throughout the body with an apparent volume of distribution of 4.9 l/kg, indicating extensive extravascular distribution. At therapeutic concentrations, aripiprazole and dehydro-aripiprazole are greater than 99 % bound to serum proteins, binding primarily to albumin.
Biotransformation
Aripiprazole is extensively metabolised by the liver primarily by three biotransformation pathways: dehydrogenation, hydroxylation, and N-dealkylation. Based on *in vitro* studies, CYP3A4 and CYP2D6 enzymes are responsible for dehydrogenation and hydroxylation of aripiprazole, and N- dealkylation is catalysed by CYP3A4. Aripiprazole is the predominant medicinal product moiety in systemic circulation. At steady state, dehydro-aripiprazole, the active metabolite, represents about 40
% of aripiprazole AUC in plasma.
Elimination
The mean elimination half-lives for aripiprazole are approximately 75 hours in extensive metabolisers of CYP2D6 and approximately 146 hours in poor metabolisers of CYP2D6.
The total body clearance of aripiprazole is 0.7 ml/min/kg, which is primarily hepatic. Following a single oral dose of [^{14}C]-labelled aripiprazole, approximately 27% of the administered radioactivity was recovered in the urine and approximately 60% in the faeces. Less than 1% of unchanged aripiprazole was excreted in the urine and approximately 18% was recovered unchanged in the faeces.
Pharmacokinetics in special patient groups
Elderly
There are no differences in the pharmacokinetics of aripiprazole between healthy elderly and younger adult subjects, nor is there any detectable effect of age in a population pharmacokinetic analysis in schizophrenic patients.
Gender
There are no differences in the pharmacokinetics of aripiprazole between healthy male and female subjects nor is there any detectable effect of gender in a population pharmacokinetic analysis in schizophrenic patients.
Smoking
Population pharmacokinetic evaluation has revealed no evidence of clinically significant effects from smoking on the pharmacokinetics of aripiprazole.
Race
Population pharmacokinetic evaluation showed no evidence of race-related differences on the pharmacokinetics of aripiprazole.
Renal impairment
The pharmacokinetic characteristics of aripiprazole and dehydro-aripiprazole were found to be similar in patients with severe renal disease compared to young healthy subjects.
Hepatic impairment
A single-dose study in subjects with varying degrees of liver cirrhosis (Child-Pugh Classes A, B, and C) did not reveal a significant effect of hepatic impairment on the pharmacokinetics of aripiprazole and dehydro-aripiprazole, but the study included only 3 patients with Class C liver cirrhosis, which is insufficient to draw conclusions on their metabolic capacity.

PHARMACEUTICAL PARTICULARS

List of Excipients

Hydroxypropyl cellulose, Microcrystalline cellulose, Mannitol, Crospovidone XL 10, Colloidal Silicon Dioxide, Magnesium stearate, Purified water.

Incompatibilities

Not applicable.

Shelf life

2 years

Storage conditions

Store below 30˚C.

Dosage Form & Packaging Available

Aripiprazole Tablets are packed in Alu-Alu blister of 10 tablets. Such blisters containing 10 tablets are packed into boxes of 1x10, 3x10 and 10x10 Tablets.

REGISTRATION NO. :

Ariptor Tablet 5 mg : MAL25106006AZ
Ariptor Tablet 10 mg : MAL18106045AZ
Ariptor Tablet 15 mg : MAL18106046AZ
Ariptor Tablet 20 mg : MAL25106007AZ

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07 August 2025

MANUFACTURER

TORRENT PHARMA

TORRENT PHARMACEUTICALS LIMITED
Ahmedabad-Mehsana Highway, Indrad, Taluka Kadi,
Dist. Mehsana, Indrad, Gujarat 382721, India.

PRODUCT REGISTRATION HOLDER

Laboratories Torrent (Malaysia) Sdn. Bhd.,
Suite E-08-08 Plaza Mont Kiara,
No. 2 Jalan Kiara, Mont Kiara,
50480 Kuala Lumpur
Malaysia.

PRODUCT NAME	:	Ariptor 5 & 20 mg	**COUNTRY :** Malaysia	**LOCATION :** Indrad	**SUPERSEDES A/W NO.:**
ITEM / PACK	:	Insert	**NO. OF COLORS:** 1	**REMARK :**	
DESIGN STYLE	:	Front/Back	**PANTONE SHADE NOS.:**	**SUBSTRATE :**	
CODE	:	xxxxxxxxx-xxxx	Black		
DIMENSIONS (MM)	:	180 x 370 mm			
ART WORK SIZE	:	S/S			
DATE	:	19-03-2026			

Activities	Department	Name	Signature	Date
Prepared By	**Pkg.Dev**			
Reviewed By	**Pkg.Dev**			
Approved By	**Quality**			