1. Name Of The Medicinal Product

ARIPIPRAZOLE TABLETS USP 10 MG

2. Qualitative And Quantitative Composition

SR. NO.	NAME OF THE INGREDIENTS	PHARMACOPEIAL SPECIFICATION	LABLE CLAIM	OVERAGES %	QTY. / TABLET	PURPOSE
ACTIVE INGREDIENTS						
1.	Aripiprazole	USP	10 mg	0.00 %	10.000 mg	API
INACTIVE INGREDIENTS						
2.	Maize starch	BP	-	0.00 %	50.000 mg	Diluent
3.	Dibasic calcium phosphate	BP	-	0.00 %	50.000 mg	Diluent
4	Magnesium stearate	BP	-	0.00 %	2.000 mg	Lubricant
5.	Purified talc	BP	-	0.00 %	2.000 mg	Glidant
6.	Sodium starch glycolate	BP	-	0.00 %	4.000 mg	Disintegrant
7.	Colloidal silicon dioxide	USP	-	0.00 %	2.000 mg	Glidant

3. Pharmaceutical Form

Oral Tablet

4. Clinical Particulars

4.1 Therapeutic Indications

Aripiprazole is primarily indicated in conditions like Schizophrenia.

4.2 Posology and Method of Administration

Aripiprazole usually is taken once a day. The usual starting dose is 10 or 15 mg once daily. The dose may be increased over time to achieve the desired effect. Aripiprazole can be taken with or without food.

4.3 Contraindications

Contraindicated in patients with a known hypersensitivity to the product.

4.4 Special Warnings and Precautions for Use

While atypical antipsychotics have not generally been associated with clinical significant prolongation of the QT interval, they should be used with care if prescribed with other drugs that increase the QT interval. It should be used with caution in patients with cardiovascular disease, or a history of epilepsy; they should be used with caution

in the elderly. It may affect performance of skilled tasks (e.g. driving). Withdrawal of antipsychotic drugs after long-term therapy should always be gradual and closely monitored to avoid the risk of acute withdrawal syndromes or rapid relapse.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

Carbamazepine can markedly decrease the amount of aripiprazole in the body by increasing the rate at which the body's enzymes (particularly the liver enzyme, CYP3A4) degrade it. The manufacturer recommends that patients on aripiprazole who are started on carbamazepine double their dose of aripiprazole, under their doctor's supervision. Other drugs that can promote the activity of CYP3A4 anddecrease the body's levels of aripiprazole are phenytoin, rifampin, and phenobarbital.
Ketoconazole can increase the amount of aripiprazole in the body by blocking CYP3A4. The manufacturer of aripiprazole recommends reducing the dose of aripiprazole by one-half during ketoconazole therapy. Many other drugs also are known to block CYP3A4 and potentially could increase the levels of aripiprazole, but their actual effects on aripiprazole levels have not been studied. Such drugs include: itraconazole, fluconazole, voriconazole, cimetidine, verapamil, diltiazem, erythromycin, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, and grapefruit juice.

4.6 Fertility, pregnancy and lactation

No data found

4.7 Effects On Ability To Drive And Use Machines

No data found

4.8 Undesirable Effects

The symptomatic adverse reactions produced by Aripiprazole are more or less tolerable and if they become severe, they can be treated symptomatically, these include Headache, Nausea, Vomiting, Tachycardia, Constipation, Insomnia, Blurred vision, Akathisia, Dyspepsia, Somnolence, Tremor, Postural hypotension, Asthenia, Light headedness, Seizures.

4.9 Overdose

Symptoms of overdose:
In clinical trials and in postmarketing experience, adverse reactions of deliberate or accidental overdosage with oral aripiprazole have been reported worldwide. These include overdoses with oral aripiprazole alone and in combination with other substances.
No fatality was reported with aripiprazole alone. The largest known dose with a known outcome involved acute ingestion of 1260 mg of oral aripiprazole (42 times the maximum recommended daily dose) by a patient who fully recovered. Deliberate or accidental overdosage was also reported in children (age 12 and younger) involving oral aripiprazole ingestions up to 195 mg with no fatalities.
Common adverse reactions (reported in at least 5% of all overdose cases) reported with oral aripiprazole overdosage (alone or in combination with other substances) 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 creatinephosphokinase increased, depressed level of consciousness, hypertension,hypokalemia, hypotension, lethargy, loss of consciousness, QRS complexprolonged, QT prolonged, pneumonia aspiration, respiratory arrest, status epilepticus, and tachycardia.

Management of overdosage

No specific information is available on the treatment of overdose with aripiprazole. An electrocardiogram should be obtained in case of overdosage and if QT interval prolongation is present, cardiac monitoring should be instituted. Otherwise, management of overdose should concentrate on supportive therapy, maintaining an adequate airway, oxygenation andventilafion, and management of symptoms. Close medical supervision and monitoring should continue until the patient recovers.

Charcoal: In the event of an overdose of aripiprazole, 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: Although there is no information on the effect of hemodialysisin treating an overdose with aripiprazole, hemodialysis is unlikely to be useful in overdose management since aripiprazole is highly bound to plasma proteins.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group:

Aripiprazole: Atypical antipsychotic

ATC code: N05AX12

MECHANISM OF ACTION

The mechanism of action of aripiprazole, as with other drugs having efficacy in schizophrenia, bipolar disorder, and agitation associated with schizophrenia or bipolar disorder, is unknown. However, it has been proposed that the efficacy of aripiprazole is mediated through a combination of partial agonist activity at D2 and 5-HT1A receptors and antagonist activity at 5-HT2A receptors. Actions at receptors other than D2, 5-HT1A, and 5-HT2A may explain some of the other clinical effects of aripiprazole, eg, the orthostatic hypotension observed with aripiprazole may be explained by its antagonist activity at adrenergic alphal receptors.

5.2 Pharmacokinetic Properties

Volume of distribution is found to be 40L or 4.9Ukg and plasma protein binding is >99% and metabolism is reported liver. Plasma half life is 75-146hrs.

5.3 Preclinical Safety Data

No data found

6. Pharmaceutical Particulars

6.1 List of Excipients

- Maize starch
- Dibasic calcium phosphate
- Magnesium stearate
- Purified talc
- Sodium starch glycolate
- Colloidal silicon dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 Months

6.4 Special Precautions for Storage

Store in a dry place at a temperature below 30°C

6.5 Nature and Contents of Container

3X10 Tablets ALU-ALU pack

6.6 Special Precautions for Disposal and Other Handling

No special requirements.

7. Marketing Authorisation Holder

West Coast Pharmaceutical Works LTD, Ahmedabad.

8. Marketing Authorisation Number(s)

Not applicable

9. Date Of First Authorisation/Renewal Of The Authorisation

Not applicable

10. Date Of Revision Of The Text

October ,2020

WEST-COAST
Pharmaceutical Works Ltd.

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