SAFETY DATA SHEET

Aripiprazole Tablets, USP 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg

EMERGENCY OVERVIEW

ARIPIPRAZOLE TABLETS, USP contain an active aripiprazole and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral tablets.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	:	Aripiprazole Tablets, USP
Potencies	:	2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg
Chemical Name	:	7-[4-[4-(2, 3 - dichlorophenyl) -1- piperazinyl] butoxy] - 3, 4 - dihydrocarbostyril
Therapeutic Category	:	A typical antipsychotic
Product Use	:	Treatment of Schizophrenia
Marketed by	:	**Ajanta Pharma USA Inc.** Bridgewater, NJ 08807. Made in India
Contact Information	:	1-855-664-7744

Section 2. Composition *I* information on ingredients

Active ingredient	:	**Exposure Limit**	**CAS No.**
Aripiprazole	:	TWA-0.3 mg/m^3	129722-12-9

TWA: Time-Weighted Average

Inactive ingredients: lactose monohydrate, magnesium stearate, microcrystalline cellulose, corn starch, hydroxyl propyl cellulose and low-substituted hydroxyl propyl cellulose.

Colorants used in the formulations are listed below:

2 mg tablets: No color.

5 mg tablets: Ferric oxide yellow.

10 mg, 15 mg, 20 mg and 30 mg: Ferric oxide red.

Section 3. Health hazards information

Potential Health Effects	**:**	**Inhalation:** The product as presented do not pose any inhalation hazard. The active material in the tablets neither known to cause adverse health effects nor irritation of the respiratory tract on inhalation. **Eye Contact:** The product as presented do not pose any ocular hazard. Although the material is not known to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. **Skin Contact:** The material is not known to be a skin irritant (as classified using animal models). Abrasive damage however, may result from prolonged exposures. **Ingestion:** Toxic if swallowed
Effects of Overexposure	**:**	The potential for exposure is reduced in finished pharmaceutical form.

Section 4. First aid measures

Inhalation	**:**	Should not pose a hazard in the final form. If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin Contact	**:**	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye Contact	**:**	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	**:**	Rinse mouth. Do not induce vomiting without medical advice. If ingestion of a large amount does occur, call a poison control center immediately
Medical Treatment	**:**	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
Over dosage	**:**	In clinical studies, and post-marketing experience, accidental or intentional acute over dosage of aripiprazole alone was identified in adult patients with estimated doses up to 1260 mg with no fatalities. The potentially medically important signs and symptoms observed in adult patients who overdosed with aripiprazole alone at doses up to 1260

mg included lethargy, blood pressure increased, somnolence, tachycardia and vomiting.

Section 5. Fire-fighting measures

Flash Point	:	Not Applicable.
Extinguishing Media	:	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Special Fire Fighting Procedures	:	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
General Fire Hazards/ Hazardous Combustible Products	:	Combustion products include carbon monoxide (CO), carbon dioxide ($C0_2$), hydrogen chloride, phosgene, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material May emit poisonous fumes. May emit corrosive fumes.

Section 6. Accidental release measures

Personal Precautions	:	Use personal protective equipment. Avoid contact with the skin and the eyes. Avoid dust formation. Ensure adequate ventilation. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
Environmental Protections	:	Prevent further leakage or spillage if safe to do so.
Clean-up Methods	:	Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/ national regulations.

Section 7. Handling and storage

Handling	:	No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	:	Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

Exposure Limits	:	TWA - 0.3 mg/m^3
Engineering Controls	:	Not required when handling tablets or containers. Ventilation should be matched to conditions.

Respiratory Protection	**:**	Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.
Personal Protection	**:**	Not required when handling tablets. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves
Recommended Facilities	**:**	Eye wash, washing facilities
General hygiene considerations		Handle in accordance with good hygiene and safety practice.

Section 9. Physical and chemical properties

Appearance **:**

Aripiprazole Tablets, USP 2 mg are white, round, biconvex beveled edged tablets engraved with 'AZ' on one side and '1' on other side. They are supplied in white HDPE bottles containing 30 tablets (NDC 27241-051-03 and 500 tablets (NDC 27241-051-08).

Aripiprazole Tablets, USP 5 mg are yellow colored, slightly mottled, round, biconvex, beveled edged tablets engraved with 'AZ' on one side and '2' on other side. They are supplied in white HDPE bottles containing 30 tablets (NDC 27241-052-03) and 500 tablets (NDC 27241-052-08).

Aripiprazole Tablets, USP 10 mg are pink colored, slightly mottled, round, biconvex, beveled edged tablets engraved with 'AZ' on one side and '3' on other side. They are supplied in white HDPE bottles containing 30 tablets (NDC 27241-053-03) and 500 tablets (NDC 27241-053-08).

Aripiprazole Tablets, USP 15 mg are pink colored, slightly mottled, square shaped, biconvex, beveled edged tablets engraved with' AZ' on one side and '4' on other side. They are supplied in white HDPE bottles containing 30 tablets (NDC 27241-054-03) and 500 tablets (NDC 27241-054-08).

Aripiprazole Tablets, USP 20 mg are pink colored, slightly mottled, modified rectangle, biconvex, beveled edged tablets engraved with 'AZ5' on one side and plain on other side. They are supplied in white HDPE bottles containing 30 tablets (NDC 27241-055-03) and 500 tablets (NDC 27241-055-08).

Aripiprazole Tablets, USP 30 mg are pink colored, slightly mottled, round, biconvex tablets engraved with 'AZ6' on one side and plain on other side. They are supplied in white HDPE bottles containing 30 tablets (NDC 27241-056-03) and 500 tablets (NDC 27241-056-08).

Other Information : Aripiprazole drug substance is a white to off-white crystalline powder. Freely soluble in methylene chloride, practically insoluble in toluene, in methanol and in water. Its pKa was established in 20% aqueous ethanol pKa = 7.6 (20% ethanol, at 25°C). The partition coefficients (Po/w) of aripiprazole range from 3.4 at pH 2.0 to > 1000 at pH 6.0 - 7.5.

Section 10. Stability and reactivity

Stability	:	Stable
Incompatibility	:	None known
Hazardous Decomposition	:	Carbon monoxide (CO), carbon dioxide (CO_2), Nitrogen oxides (NOx), Hydrogen chloride.
Conditions to Avoid	:	Heat, flames and sparks
Hazardous Polymerization	:	Not Known. It undergoes degradation on heating.

Section 11. Toxicological information

Acute toxicity	:	Product is toxic on ingestion. LD50 of Aripiprazole is reported as 196 mg/kg (rat, oral).
Carcinogenesis	:	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Mutagenesis	:	2,3-DCPP was clast genic in the *in vitro* chromosomal aberration assay in Chinese hamster lung (CHL) cells with and without metabolic activation.
Impairment of Fertility	:	No effect on fertility in female and male rats were observed.

Section 12. Ecological information

Eco toxicity of API	:	The API in tablet dosage form is not expected to present significant adverse environmental effects.
In the finished product form	:	There is no potential for air borne contamination since the product is in consolidated form as compressed tablet.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: Discard away from children's reach.

Section 14. Transport information

This product is not subject to the regulations for the safe transport of hazardous chemicals

DOT: Not regulated for transport of dangerous goods.
IATA: Not regulated for transport of dangerous goods
IMDG: Not regulated for transport of dangerous goods

Section 15. Regulatory information

DEA: Not Available.
FDA: Aripiprazole is an approved prescription medication.
Inventory Status: This material is not listed on the US TSCA Inventory

Section 16. Disclaimer

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

Date: April 07, 2022

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION