



**SQUARE PHARMACEUTICALS LTD
DHAKA UNIT**

SAFETY DATA SHEET

PART I: What is the material and what do I need to know in an emergency?

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE

IDENTIFICATION of the SUBSTANCE or PREPARATION:

Trade Name: Aripiprazole Orally Disintegrating Tablets, USP

Generic Name: Aripiprazole USP

Chemical Name API (IUPAC): 7-[4-[4-(2,3-dichlorophenyl)-1-piperazinyl]butoxy]-3,4-dihydrocarbostyryl

Chemical Formula of API: $C_{23}H_{27}Cl_2N_3O_2$

Legal Category: Prescription Only Medicine (POM).

Therapeutic Class: Atypical antipsychotic

Therapeutic action and Use: Treatment of Schizophrenia and Tourette's disorder

Relevant Use of the Product: Human Pharmaceuticals

How Supplied:

NDC: 72578-106-06: 10 mg; 30 Tablets/Bottle

NDC: 72578-107-06: 15 mg; 30 Tablets/Bottle

COMPANY/UNDERTAKING IDENTIFICATION:

SQUARE PHARMACEUTICALS LTD.

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2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture: This substance does not meet the classification criteria of the EC Directives 67/548/EEC, 1999/45/EC or 1272/2008.

Label elements: The product does not need to be labeled in accordance with EC directives or respective national laws.

Other hazards: None



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3. COMPOSITION AND INFORMATION ON INGREDIENTS

Composition:

Active Ingredient	Content	
Aripiprazole USP	10 mg	Each Tablet contains Aripiprazole USP 10 mg
	15 mg	Each Tablet contains Aripiprazole USP 15 mg
Inactive ingredients	10 mg	Mannitol USP (Pearlitol 200 SD), Crospovidone NF (Polyplasdone XL), Aspartame NF, Peppermint Flavour 501500 TP 0504 Ph. Grade, Calcium Stearate NF
	15 mg	Mannitol USP (Pearlitol 200 SD), Crospovidone NF (Polyplasdone XL), Aspartame NF, Peppermint Flavour 501500 TP 0504 Ph. Grade, Calcium Stearate NF

PART II: What should I do if a hazardous situation occurs?

4. FIRST AID MEASURES

Description of First Aid Measures:

- **General advice:** Consult a doctor and show this safety data sheet.
- **If inhaled:** Remove to fresh air and monitor breathing. If breathing becomes difficult, give oxygen. If breathing stops, give artificial respiration. Consult a doctor.
- **In case of skin contact:** Immediately wash skin with copious amounts of soap and water for at least 15 minutes. Remove contaminated clothing and shoes and wash before reuse. Consult a doctor.
- **In case of eye contact:** Flush with copious amounts of water for at least 15 minutes. Consult a doctor.
- **If swallowed:** Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Consult a doctor.

Most important symptoms and effects, both acute and delayed

To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Indication of immediate medical attention and special treatment needed

Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.

5. FIRE AND EXPLOSION DATA

Extinguishing media

- **Suitable Extinguishing Media:** Use water spray, dry chemical, foam, and carbon dioxide fire extinguisher.

Special hazards arising from the substance or mixture: During combustion, may emit irritant fumes

Advice for firefighters: Wear self-contained breathing apparatus and protective clothing.



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6. ACCIDENTAL RELEASE MEASURE

Protective Precautions, Protective Equipment and Emergency Procedures:

- Do not take action without suitable protective clothing - see section 8 of SDS. Evacuate personnel to safe areas. Ensure adequate ventilation. Avoid breathing vapors, mist, dust or gas.

Environmental Precautions: Do not let product enter drains

Methods and Material For Containment and Cleaning Up:

- Cover spillage with suitable absorbent material. Using non-spark tools, sweep up material and place in an appropriate container. Decontaminate spill site with 10% caustic solution and ventilate area until after disposal is complete. Hold all material for appropriate disposal as described under section 13 of SDS.

PART III: How can I prevent hazardous situations from occurring?

7. HANDLING AND STORAGE

Precautions To Be Taken in Handling:

- Use in a chemical fume hood, with air supplied by an independent system. Avoid inhalation, contact with eyes, skin and clothing. Avoid the formation of dust and aerosols. Use in a well-ventilated area. Keep away from sources of ignition.
- Avoid prolonged or repeated exposure.

Precautions To Be Taken in Storing: Store as directed by product packaging.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

- **Components with workplace control parameters:** Contains no substances with occupational exposure limit values

Exposure controls:

- **Appropriate engineering controls:** Use in a fume hood where applicable. Ensure all engineering measures described under section 7 of SDS are in place. Ensure laboratory is equipped with a safety shower and eye wash station.
- **Personal protective equipment**
 - Eye/face protection:** Use appropriate safety glasses
 - Skin protection:** Use appropriate chemical resistant gloves (minimum requirement use standard BS EN 374:2003). Gloves should be inspected before use. Wash and dry hands thoroughly after handling.
 - Body protection:** Wear appropriate protective clothing
 - Respiratory protection:** If risk assessment indicates necessary, use a suitable respirator.



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9. PHYSICAL AND CHEMICAL PROPERTIES

Parameters	Aripiprazole Orally Disintegrating Tablets USP, 10 mg	Aripiprazole Orally Disintegrating Tablets USP, 15 mg
Appearance	Aripiprazole Orally Disintegrating Tablets USP, 10 mg are white to off-white, capsule-shaped, uncoated tablets debossed with 'ZF 41' on one side and plain on the other side.	Aripiprazole Orally Disintegrating Tablets USP, 15 mg are white to off-white, round-shaped, biconvex, uncoated tablets debossed with 'ZF 42' on one side and plain on other side
Color	White to off-white	White to off-white

10. STABILITY AND REACTIVITY DATA

Reactivity: Stable under recommended transport or storage conditions.

Chemical Stability: Stable under recommended storage conditions.

Possibility of hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions. Decomposition may occur on exposure to conditions or materials listed below.

Conditions to Avoid: Heat, moisture.

Incompatibility Materials: Strong acids/alkalis, strong oxidizing/reducing agents.

Hazardous decomposition products: In combustion may emit toxic fumes. No known decomposition information.

PART IV *Is there any other useful information about this material?*

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects:

- **Acute toxicity:** Classified based on available data. For more details, see section 2.
- **Skin corrosion/irritation:** Classified based on available data. For more details, see section 2.
- **Serious eye damage/irritation:** Classified based on available data. For more details, see section 2.
- **Respiratory or skin sensitization:** Classified based on available data. For more details, see section 2.
- **Germ cell mutagenicity:** Classified based on available data. For more details, see section 2.
- **Carcinogenicity:** Classified based on available data. For more details, see section 2.
- **Reproductive toxicity:** Classified based on available data. For more details, see section 2.
- **Specific target organ toxicity - single exposure:** Classified based on available data. For more details, see section 2.
- **Specific target organ toxicity - repeated exposure:** Classified based on available data. For more details, see section 2.
- **Aspiration hazard:** Classified based on available data. For more details, see section 2.
- **Additional Information RTECS No:** not available. Exposure may cause irritation of eyes, mucous membranes, upper respiratory tract and skin. To the best of our knowledge, the chemical, physical and toxicological properties have not been fully investigated.

12. ECOLOGICAL INFORMATION

Toxicity: No data available

Persistence and Degradability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Results of PBT and vPvB assessment: PBT/vPvB assessment unavailable as chemical safety assessment not required or not conducted

Other adverse effects: No data available.



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13. DISPOSAL CONSIDERATION

Waste Disposal Method:

- **Product:** Dispose in accordance with local, state, and federal regulations
- **Contaminated packaging:** Conduct recycling or disposal in accordance with prevailing local, state and federal regulations.

14. TRANSPORTATION INFORMATION

Classified according to the criteria of the UN Model Regulations as reflected in the IMDG Code, ADR, RID and IATA.

- **UN-Number:** Does not meet the criteria for classification as hazardous for transport.
- **UN proper shipping name:** Does not meet the criteria for classification as hazardous for transport.
- **Transport hazard class(es):** Does not meet the criteria for classification as hazardous for transport.
- **Packaging group:** Does not meet the criteria for classification as hazardous for transport.
- **Environmental hazards:** This product is not classified as environmentally hazardous according to the UN Model Regulations, nor a marine pollutant according to the IMDG Code.
- **Special precautions for users:** No data available.

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 453/2010.

- **Safety, health and environmental regulations/legislation specific for the substance or mixture TSCA (Toxic Substance Control Act):** No data available.
- **SARA 313 Components:** No data available.
- **SARA 311/312 Hazards:** No data available.
- **Massachusetts Right To Know Components:** No components are subject to the Massachusetts Right to Know Act.
- **Pennsylvania Right To Know Components:** No components are subject to the Pennsylvania Right to Know Act.
- **New Jersey Right To Know Components:** No components are subject to the New Jersey Right to Know Act.
- **California Prop. 65 Components:** No data available.

Chemical safety assessment: A Chemical Safety Assessment has not been made for this product

16. OTHER INFORMATION

SDS Creation Date: 08 May 2022

SDS Version Number: 1

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall SQUARE Pharmaceuticals Ltd. be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if SQUARE Pharmaceuticals Ltd. has been advised of the possibility of such damages.

End of Safety Data
