ajanta pharma limited

SAFETY DATA SHEET

DULOXETINE DELAYED-RELEASE CAPSULES 20 mg, 30 mg, 40 mg and 60 mg

EMERGENCY OVERVIEW

DULOXETINE DELAYED-RELEASE CAPSULES contain active drug substance Duloxetine Hydrochloride 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 route.

WARNING: Accidental ingestion of large amounts may be harmful.

Section 1. Identification of the substance

Identification of the product

Product name	**:**	DULOXETINE DELAYED-RELEASE CAPSULES
Chemical Formula	**:**	Duloxetine Hydrochloride : $C_{18}H_{19}NOS.HCL$
Chemical Name	**:**	**Duloxetine Hydrochloride:** (+)-(S)-N-methyl-γ-(1-naphthyloxy)-2-thiophenepropylamine hydrochloride
Therapeutic Category	**:**	Anti-depressant
Marketed by	**:**	**Ajanta Pharma USA Inc.** 440 US Highway 22 East, Bridgewater, NJ 08807. Made in India
Contact Information	**:**	1-855-664-7744

Section 2. Hazard (s) Identification

Potential Health Effects	**:**	**Inhalation:** Not expected to be hazardous in final pharmaceutical form. **Eye Contact:** Not expected to be hazardous in final pharmaceutical form. **Skin Contact:** Not expected to be hazardous in final pharmaceutical form. **Indigestion:** Health injuries are not known or expected under normal use. Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful.
Effects of Overexposure	**:**	The potential for exposure is reduced in finished pharmaceutical dosage form.

Section 3. Composition / information on ingredients

Active ingredient	Exposure Limit	CAS No.
Duloxetine Hydrochloride	Not Found	136434-34-9

Inactive ingredients: Each capsule contains the inactive ingredients which includes sugar spheres, hypromellose, sucrose, talc, methacrylic acid copolymer dispersion and triethyl citrate. The capsule shell contains gelatin, FD&C Red No. 3 (40 mg), FD&C Blue No. 1 (40 mg), FD&C Blue No. 2 (20 mg, 30 mg, 60 mg), titanium dioxide, and sodium lauryl sulfate.

For 20 mg, 30 mg, 40 mg (body & cap) and 60 mg (body only) strengths, imprinting black ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, black iron oxide, potassium hydroxide and purified water.

For 60 mg (cap only) strength, imprinting white ink contains shellac, dehydrated alcohol, isopropyl alcohol, butyl alcohol, propylene glycol, strong ammonia solution, purified water, potassium hydroxide, and titanium dioxide.

Section 4. First-aid measures

The product is a delayed release capsule dosage form does not pose a problem of exposure to active drug substance and should not cause inhalation, skin and eye irritation problem. However, in case of exposure:

Eye Contact	:	Immediately flush eyes with water for at least 15 minutes. Get medical attention.
Skin Contact	:	Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
Ingestion	:	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. DO NOT induce vomiting unless directed to do so by medical personnel.
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	:	There is no specific antidote to duloxetine, but if serotonin syndrome ensues, specific treatment (such as with cyproheptadine and/or temperature control) may be

considered. In case of acute overdose, treatment should consist of those general measures employed in the management of overdose with any drug.
An adequate airway, oxygenation, and ventilation should be assured, and cardiac rhythm and vital signs should be monitored. Induction of emesis is not recommended.
Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion or in symptomatic patients.
Activated charcoal may be useful in limiting absorption of duloxetine from the gastrointestinal tract.
Administration of activated charcoal has been shown to decrease AUC and Cmax by an average of one third, although some subjects had a limited effect of activated charcoal. Due to the large volume of distribution of this drug, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be beneficial In managing overdose, the possibility of mUltiple drug involvement should be considered. A specific caution involves patients who are taking or have recently taken duloxetine and might ingest excessive quantities of a TCA. In such a case, decreased clearance of the parent tricyclic and/or its active metabolite may increase the possibility of clinically significant sequelae and extend the time needed for close medical observation.

Section 5. Fire-fighting measures

Flash Point	**:**	Not Reported
Extinguishing Media	**:**	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
General Fire Hazards/ Hazardous Combustible Products	**:**	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
Special Fire Fighting Procedures	**:**	Wear self-contained breathing apparatus pressure demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.

Section 6. Accidental release measures

Personal Precautions	**:**	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Protections	**:**	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Clean-up Methods	**:**	Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains.
Additional Consideration for Large Spills	**:**	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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. If capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin and clothing. Use adequate ventilation. Minimize dust generation and accumulation.
Storage	**:**	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Section 8. Exposure controls / personal protection

Respiratory Protection	**:**	Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.
Skin Protection	**:**	Skin protection is not normally necessary, however it is good practice to avoid direct contact with chemical to use suitable gloves when handling.
Eye protection	**:**	Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.
Protective Clothing	**:**	Protective clothing is not normally necessary, however it is good practice to use apron.

Section 9. Physical and chemical properties

Appearance	**:**	**Duloxetine Delayed-Release Capsules 20 mg** are White/Blue hard gelatin capsules of size "4" with "DLX 20" imprint on body and "ap" logo imprint on cap with black color ink and containing white to off white pellets. **Duloxetine Delayed-Release Capsules 30 mg** are Blue/Blue hard gelatin capsules of size "3" with "DLX

30" imprint on body and "ap" logo imprint on cap with black color ink and containing white to off white pellets. **Duloxetine Delayed-Release Capsules 40 mg** are Pink/Blue hard gelatin capsules of size "3" with "DLX 40" imprint on body and "ap" logo imprint on cap with black color ink and containing white to off white pellets. **Duloxetine Delayed-Release Capsules 60 mg** are White/Blue hard gelatin capsules of size "1" wjth "DLX 60" imprint on body with black color ink and "ap" logo imprint on cap with white color ink and containing white to off white pellets.

Presentations and NDC Codes	**Strengths**			
	20 mg	**30 mg**	**40 mg**	**60 mg**
Bottles of 30’s pack	NA	27241-098-03	27241-164-30	27241-099-03
Bottles of 60’s pack	27241-097-06	NA	NA	NA
Bottles of 90’s pack	27241-097-90	27241-098-09	NA	27241-099-40
Bottles of 500's pack	27241-097-05	NA	NA	NA
Bottles of 1000’s pack	27241-097-10	27241-098-10	NA	27241-099-90

Solubility in water : No Data Available
Odor : Odorless
Boiling point : No Data Available
Melting Point : No Data Available
Evaporation rate : No Data Available
Specific gravity : No Data Available
Vapor density : No Data Available
Reactivity in water : No Data Available
Evaporation rate : No Data Available
Percentage Volatile by volume : No Data Available
Vapor pressure : No Data Available
Other information : **Duloxetine Hydrochloride, USP** is white to brownish white solid, which is slightly soluble in water.

Section 10. Stability and reactivity

Condition to avoid	**:**	Avoid exposure to extreme heat, light and moisture.
Stable	**:**	Stable under normal ambient and anticipated storage and handling conditions.
Decomposition Products	**:**	No data available
Hazardous Reaction	**:**	No data available. In finished dosage form there is least possibility that product will undergo any hazardous reaction.
Incompatibilities	**:**	No data available.

Section 11. Toxicological information

General	**:**	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Target organ	**:**	Eye contact, Skin contact and inhalation is not great risk as this product is orally administered capsule formulation.
Acute Toxicity	**:**	**Duloxetine Hydrochloride** Rat (M) Oral LD50 491 mg/kg Rat (F) Oral LD50 279 mg/kg

Section 12. Ecological information

No data available on Ecotoxicity of API. In the finished product form there is no potential for air borne contamination since the product is in capsule form.

Section 13. Disposal Consideration

Waste Disposal Considerations: Dispose of 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 authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.
DOT: Not Regulated
IATA: Not Regulated
IMDG: Not Regulated

Section 15. Regulatory information

DEA: Duloxetine Hydrochloride is not a controlled substance.

FDA: Duloxetine Hydrochloride Delayed-Release Capsule is an approved prescription medication.

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: August 25, 2022

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION