ajanta pharma limited

SAFETY DATA SHEET

Sildenafil Tablets, USP 25 mg, 50 mg and 100 mg

EMERGENCY OVERVIEW

Sildenafil Tablets contain an active drug substance Sildenafil Citrate USP 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	**:**	Sildenafil Tablets, USP
Potencies	**:**	25 mg, 50 mg and 100 mg
Chemical Name	**:**	1-[[3-(6,7-dihydro-1-methyl-7-oxo-3-propyl-1H-pyrazolo [4,3-d]pyrimidin-5-yl)-4-ethoxyphenyl]sulfonyl]-4-methylpiperazine citrate.
Therapeutic Category	**:**	Phosphodiesterase-5 (PDE5) inhibitor.
Product Use	**:**	Treatment of Erectile dysfunction.
Marketed by	**:**	Ajanta Pharma USA Inc. Bridgewater, NJ 08807. Made in India
Contact Information	**:**	855-664-7744

Section 2. Health hazards information

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. **Ingestion:** 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

Components Active ingredient	Exposure Limit	CAS No.
Sildenafil Citrate USP	Not available.	171599-83-0

Inactive ingredients: Each tablet contains multiple functional inactive ingredients such as microcrystalline cellulose, anhydrous dibasic calcium phosphate, croscarmellose sodium, magnesium stearate, colloidal silicon dioxide, hypromellose, hydroxypropyl cellulose, polyethylene glycol, titanium dioxide, FD & C Blue #1/brilliant blue FCF aluminum lake, D & C yellow # 10 aluminum lake.

Section 4. First aid measures

The product is a film coated tablet and in the final dosage form (Tablets) 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.
Inhalation	:	Remove to fresh air. If not breathing, give artificial respiration or oxygen by trained personnel. Get immediate medical attention 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 studies with healthy volunteers when dosed up to 800 mg in a single dose, showed similar adverse event to those seen at lower doses but incidence rates and severities were increased. In cases of overdose, standard supportive measures should be adopted as required. Renal dialysis is not expected to accelerate clearance as sildenafil, USP is

highly bound to plasma proteins and it is not eliminated in the urine.

Section 5. Fire-fighting measures

Flash Point	:	Not available.
Extinguishing Media	:	Extinguish fires with CO2, extinguishing powder, foam, or water.
General Fire Hazards/ Hazardous Combustible Products	:	Formation of toxic gases is possible during heating or 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 tablets 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°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

Section 8. Exposure controls/personal protection

Exposure Limits : $350\mu g/m^3$

Engineering Controls : For consumer use, no unusual precaution are necessary for handling packets. In laboratory, medical or industrial setting use appropriate ventilation.

Respiratory Protection : For consumer use, no unusual precaution are necessary. However, for handling packets, in laboratory, medical or industrial setting use NIOSH/MSHA approved respirators for protection if necessary.

Personal Protection : For consumer use, no unusual precaution are necessary. However, for handling packets in laboratory, medical or industrial setting use gloves as recommended.

Recommended Facilities : None

Section 9. Physical and chemical properties

Appearance : Sildenafil citrate, USP is supplied as green, oval-shaped, beveled edge, biconvex, film-coated tablets containing sildenafil citrate, USP equivalent to the nominally indicated amount of sildenafil, USP and debossed on the obverse and reverse sides as follows:

	25 mg	50 mg	100 mg
Obverse	25	50	100
Reverse	SC	SC	SC
Bottle of 30 with child- resistant closure	NDC-27241-067-03	NDC-27241-068-03	NDC-27241-069-03
Bottle of 100 with child- resistant closure	N/A	NDC-27241-068-10	NDC-27241-069-10

Other Information : Sildenafil citrate USP is a white to off-white crystalline powder with a solubility of 3.5 mg/mL in water and a molecular weight of 666.7.

Section 10. Stability and reactivity

Stability	:	Stable
Incompatibility	:	Incompatible with strong oxidizing agent.
Hazardous Decomposition	:	Data not available.
Conditions to Avoid	:	Incompatible materials, strong oxidants.

Section 11. Toxicological information

Acute toxicity	:	Rat Oral LDmin. 300-500 mg/kg Mouse Oral LDmin. 500-1000 mg/kg Rat Dermal LD50 > 2000 mg/kg
Carcinogenesis	:	None of the components of this product are suspected to be a carcinogen.
Mutagenesis	:	When processed and used as directed, this product is not expected to produce mutagenic effects in humans.
Impairment of Fertility	:	Based on available data, the classification criteria are not met.

Section 12. Ecological information

Eco toxicity of drug substance	:	In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater.
In the finished product form	:	There is no potential for air borne contamination since the drug substance is in consolidated form as tablets.

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: If pharmacy service available, return unused tablets to pharmacy for disposal. 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: Sildenafil Tablets, USP 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: March 31, 2022

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION