

SAFETY DATA SHEET

TADALAFIL TABLETS, USP 2.5 mg, 5 mg, 10 mg and 20 mg

EMERGENCY OVERVIEW

TADALAFIL TABLETS contain active drug substances tadalafil 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	: TADALAFIL TABLETS, USP 2.5 mg, 5 mg, 10 mg and 20 mg
Chemical Formula	: TADALAFIL: C ₂₂ H ₁₉ N ₃ O ₄
Chemical Name	: Tadalafil: pyrazino[1',2':1,6]pyrido[3,4-b]indole-1,4-dione, 6-(1,3-benzodioxol-5-yl)2,3,6,7,12,12a-hexahydro-2-methyl-, (6R,12aR)-
Therapeutic Category	: Pulmonary arterial hypertension, Erectile dysfunction
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.
Tadalafil	Not Found	171596-29-5

Inactive ingredients: Each tablet contains microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, sodium lauryl sulfate, low substituted hydroxypropyl cellulose and magnesium stearate.

The color coating contains hypromellose, titanium dioxide, lactose monohydrate, iron oxide yellow, triacetin and FD&C yellow #5 /tartrazine aluminium lake.

Section 4. First-aid measures

Eye Contact:	: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Never give anything by mouth to an unconscious person.
Skin Contact:	: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion:	: Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	: Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Overdose Treatment	: Consult with a Certified Poison Control Center (1-800-222-1222) for up-to-date guidance and advice

Section 5. Fire-fighting measures

Flash Point	: Not Reported
Extinguishing Media	: Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.
Fire and Explosion Hazard	: This material is assumed to be combustible. Keep it away from the open fires.
Fire Fighting Procedures	: As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

Hazardous Combustion by Products : Carbon dioxide, carbon monoxide, oxides of nitrogen, oxides of sulfur, oxides of sodium, hydrogen chloride

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

- General Handling** : Minimize dust generation and accumulation. If tablets are crushed and/or broken, avoid breathing dust and avoid contact to eyes, skin and clothing. When handling, use appropriate personal protective equipment.
- Storage** : Tadalafil Tablets should be stored at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
Keep out of reach of children.

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
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Appearance : **2.5 mg:** Light yellow to yellow colored, oval-shaped, film-coated tablets, debossed with “T2^{1/2}” on one side and plain on other side.
5 mg: Light yellow to yellow colored, oval-shaped, film-coated tablets, debossed with “T5” on one side and plain on other side.
10 mg: Light yellow to yellow colored, oval-shaped, film-coated tablets, debossed with “T10” on one side and plain on other side.
20 mg: Light yellow to yellow colored, oval-shaped, film-coated tablets, debossed with “T20” on one side and plain on other side.

Presentations and NDC Codes	Strengths			
	2.5 mg	5 mg	10 mg	20 mg
Bottles of 30's pack	27241-111-03	27241-112-03	27241-113-03	27241-114-03
Bottles of 500's pack	27241-111-05	27241-112-05	27241-113-05	27241-114-05

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 : No Data Available

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 tablet formulation.
- Acute Toxicity** : Tadalafil
Oral (Rat) > 2000 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 compressed tablet 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: Tadalafil is not a controlled substance.

FDA: Tadalafil 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