Alembic Pharmaceuticals Limited

Safety Data Sheet
According to Regulation (EC) No. 1907/2006
Updated on 14-01-2026

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product name	:	Dapagliflozin Tablets 5 mg and 10 mg
CAS No.	:	--
Identified uses	:	Dapagliflozin tablet is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated: · To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors. · As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Company	:	Alembic Pharmaceuticals Limited Alembic Road, Vadodara, Gujarat, INDIA-390 003
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Emergency Phone #	:	

2. HAZARDS IDENTIFICATION

Fire and Explosion: Not available

Environment No information is available about the potential of this product to produce adverse environmental effects.

Warnings:

- Diabetic Ketoacidosis in Patients with Type 1 Diabetes Mellitus and Other Ketoacidosis: Consider ketone monitoring in patients with type 1 diabetes mellitus and consider ketone monitoring in others at risk for ketoacidosis, as indicated.
- Volume depletion: Before initiating dapagliflozin, assess volume status and renal function in the elderly, patients with renal impairment or low systolic blood pressure, and in patients on diuretics.
- Urosepsis and Pyelonephritis: Evaluate for signs and symptoms of urinary tract infections and treat promptly, if indicated.
- Hypoglycemia: Consider a lower dose of insulin or the insulin secretagogue to reduce the risk of hypoglycemia when used in combination with dapagliflozin.

Adverse Reactions:

Most common adverse reactions (5% or greater incidence) were female genital mycotic infections, nasopharyngitis, and urinary tract infections.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Dapagliflozin, an inhibitor of SGLT2, is described chemically as D-glucitol, 1,5-anhydro-1-C-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-, (1S). The empirical formula is C21H25ClO6 and the molecular weight is 408.87.

Dapagliflozin tablets are available as a film-coated tablet for oral administration containing 5 mg dapagliflozin or 10 mg dapagliflozin, and the following inactive ingredients: anhydrous lactose, colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate and microcrystalline cellulose. In addition, the film coating contains the following inactive ingredients: iron oxide yellow, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

4. FIRST AID MEASURES

Description of first aid measures

General advice - Consult a physician. Show this safety data sheet to the doctor in attendance.

Eye Contact

Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Inhalation

Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Ingestion

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards: Assume that this product is capable of sustaining combustion.

Extinguishing Media: Water spray, carbon dioxide, dry chemical powder or appropriate foam.

Special Firefighting Procedures:

For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

Hazardous Combustion Products: Hazardous combustion or decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Wear respiratory protection. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental Precautions

Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Dapagliflozin tablets 5 mg, are yellow, biconvex, round with 'L644' debossed on one side and plain on the other side.

Bottle of 30 capsules with child-resistant closure, NDC 62332-392-30
Bottle of 1000, NDC 62332-392-91

Dapagliflozin tablets 10 mg, are yellow, biconvex, diamond with 'L645' debossed on one side and plain on the other side.
Bottle of 30 capsules with child-resistant closure, NDC 62332-393-30
Bottle of 1000, NDC 62332-393-91

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: No data available.

Possibility of Hazardous Reactions: No data available

Oxidizing Properties: No data available

Incompatible Materials: No data available

Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Dapagliflozin did not induce tumors in either mice or rats at any of the doses evaluated in 2-year carcinogenicity studies. Oral doses in mice consisted of 5, 15, and 40 mg/kg/day in males and 2, 10, and 20 mg/kg/day in females, and oral doses in rats were 0.5, 2, and 10 mg/kg/day for both males and females. The highest doses evaluated in mice were approximately 72-times (males) and 105-times (females) the clinical dose of 10 mg per day, based on AUC exposure. In rats, the highest dose was approximately 131-times (males) and 186-times (females) the clinical dose of 10 mg per day, based on AUC exposure.

Dapagliflozin was negative in the Ames mutagenicity assay and was positive in a series of in vitro clastogenicity assays in the presence of S9 activation and at concentrations greater than or equal to 100 µg/mL. Dapagliflozin was negative for clastogenicity in a series of in vivo studies evaluating micronuclei or DNA repair in rats at exposure multiples greater than 2100-times the clinical dose.

There was no carcinogenicity or mutagenicity signal in animal studies, suggesting that dapagliflozin does not represent a genotoxic risk to humans.

Dapagliflozin had no effects on mating, fertility, or early embryonic development in treated male or female rats at exposure multiples less than or equal to 1708-times and 998-times the maximum recommended human dose in males and females, respectively.

12. ECOLOGICAL INFORMATION

Toxicity
No data available

Persistence and degradability
No data available

Bio accumulative potential
No data available

Mobility in soil
No data available

Results of PBT and vPvB assessment
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

DOT: Not regulated

ICAO/IATA: Not regulated

IMDG: Not regulated

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available

Chemical Safety Assessment
No data available.

16. OTHER INFORMATION

Further information
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide for technically qualified personnel. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Alembic Pharmaceuticals Ltd. extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third-party use & shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.