Safety Data Sheet **Revision No.:** 00
Ursodiol Tablets, USP
Strength: 250/500mg **Pack Size: 250 mg:** 100/500 Tablets per bottle

500 mg: 100/500 Tablets per bottle

EMERGENCY OVERVIEW

Each Ursodiol Tablets, USP intended for oral administration contains Ursodiol and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

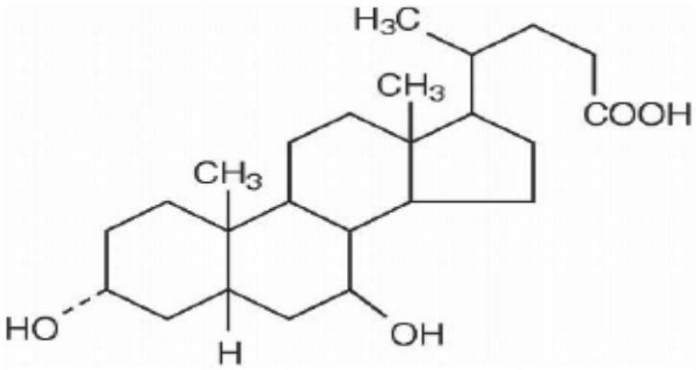
Section 1. IDENTIFICATION

Identification of the product

Product Name: Ursodiol Tablets, USP

Formula: $C_{24}H_{40}O_4$

Chemical Name: 3α, 7ß-dihydroxy-5ß-cholan-24-oic acid



Manufacturer / Supplier identification

Company:	**Cadila Healthcare Limited Baddi, India**
Address:	Cadila Healthcare Limited, Swaraj Majra, Judi Kalan, Post - Baddi, Tehsil - Nalagarh, District - Solan, Himachal Pradesh 173205.
Contact for information:	Tel: +91-1795-246841 Fax: +91-1795-246842
Emergency Telephone No.	Tel: +91-1795-246841
Recommended use /	
Therapeutic Category	**T**reatment of patients with primary biliary cirrhosis.
Restriction on Use / Contraindications:	Patients with complete biliary obstruction and known hypersensitivity or intolerance to Ursodiol or any of the components of the formulation.

Section 2. HAZARD(S) IDENTIFICATION

Dose and Administration	Dosage should be individualized with careful monitoring of patient response. The recommended adult dosage for Ursodiol tablets USP, 250 mg and 500 mg in the treatment of PBC is 13-15 mg/kg/day administered in two to four divided doses with food. Dosing regimen should be adjusted according to each patient's need at the discretion of the physician.
Adverse Effects	Most common adverse reactions reported with the use of Ursodiol during worldwide post marketing and clinical experience (≥1%) are, in alphabetical order: abdominal discomfort, abdominal pain, alopecia, diarrhea, nausea, pruritus, and rash.
Over Dose Effect	There have been no reports of accidental or intentional over dosage with Ursodiol. Single oral doses of Ursodiol at 10 g/kg in mice and dogs, and 5 g/kg in rats were not lethal. A single oral dose of Ursodiol at 1.5 g/kg was lethal in hamsters. Symptoms of acute toxicity were salivation and vomiting in dogs, and ataxia, dyspnea, ptosis, agonal convulsions and coma in hamsters.
Contraindications	Patients with complete biliary obstruction and known hypersensitivity or intolerance to Ursodiol or any of the components of the formulation
Pregnancy Comments	There are no adequate or well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Reproduction studies have been performed in pregnant rats at oral doses up to 22 times the recommended maximum human dose (based on body surface area) and in pregnant rabbits at oral doses up to 7 times the recommended maximum human dose (based on body surface area) and have revealed no evidence of impaired fertility or harm to the fetus due to Ursodiol.
Pregnancy Category	Pregnancy Category B

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Exposure Limit	CAS No.
Principle Component:		
Ursodiol	Not Found	128-13-2
Inactive Ingredients:		
Microcrystalline Cellulose	Not Found	9004-34-6
Sodium Starch Glycolate	Not Found	9063-38-1
Polyethylene Glycol 8000	Not Found	25322-68-3
Povidone	Not Found	9003-39-8
Colloidal Silicon Dioxide	Not Found	7631-86-9
Magnesium Stearate	Not Found	557-04-0
Opadry White	Not Found	889676-18-0
Sodium Lauryl Sulfate	Not Found	151-21-3

Section 4. FIRST-AID MEASURES

Inhalation	Remove to fresh air. If discomfort occurs or persists, get medical attention.
Skin contact	Remove contaminated clothing and shoes. Wash skin with soap and plenty of water. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.
Eye contact	Immediately flush eyes with plenty of water. If irritation occurs or persists, get medical attention.
Ingestion	If large quantities of this material are swallowed, get medical attention immediately. If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Section 5. FIRST FIGHTING MEASURES

Flash Point	Not available
Extinguishing Media	Water, Dry Chemical, Foam.
Unusual Fire and Explosion Hazards	Toxic emissions may be given off in a fire.
Fire Fighting Instructions	Wear NIOSH/MSHA approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire. Use water to keep fire exposed containers cool.

Section 6. ACCIDENTAL RELEASE MEASURES

Spill Clean Up Procedures	Use proper personal protective equipment and clothing. Shut off the source of the spill or leak if it is safe to do so. Scoop or shovel spilled material into a suitable labeled open head drum. Secure the drum cover and move the container to a safe holding area. Wash spill area thoroughly with soapy water.
Treatment and Disposal	Decontaminate equipment. Dispose of protective clothing with spilled material.
Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

Section 7. HANDLING AND STORAGE

Storage	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight container.
Precautions for safe handling	Avoid prolonged exposure. Avoid contact with eyes. Avoid release to environment. Use with adequate ventilation. When handling, use proper personal protective equipment. Wash thoroughly after handling. Keep container tightly closed when not in in use.

Section 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Skin protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredients(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
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.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Solid
Color	**250 mg/500mg:** White to off-white
Odor	No unpleasant odor.
Pure/Mixture	Mixture

Section 10. STABILITY AND REACTIVITY

Stability	Normally stable but formation of toxic gases is possible during heating or in case of fire.
Incompatibility materials to avoid	keep away from Oxidizing agents
Polymerization	No
Conditions of Polymerization	Will not occur

Section 11. TOXILOGICAL INFORMATION

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	May cause an allergic skin reaction.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.

In two 24-month oral carcinogenicity studies in mice, Ursodiol at doses up to 1,000 mg/kg/day (3,000 mg/m2/day) was not tumorigenic.

Ursodiol at oral doses of up to 2,700 mg/kg/day (16,200 mg/m2/day, 29 times the recommended maximum human dose based on body surface area) was found to have no effect on fertility and reproductive performance of male and female rats.

Section 12. ECOLOGICAL INFORMATION

Do not allow product to enter drinking water supplies, waste water or soil.

Section 13. DISPOSAL CONSIDERATION

Disposal Recommendations Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. TRANSPORT INFORMATION

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. REGULATORY INFORMATION

Generic Medicine, ANDA Number 211145

Section 16. OTHER INFORMATION

Additional Information

NFPA Rating: These ratings are based on NFPA code 704 and are intended for use by emergency personnel to determine the immediate hazards of a material

Health……..1

Fire……..1

Reactivity…0

Date of issue: May 31, 2018 **Supersedes edition:** New Edition

The information presented in the safety data sheet is, to the best our knowledge, accurate and reliable. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.