

SAFETY DATA SHEET**Product Name** Clobazam Tablets 10 mg and 20 mg

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1. Product information**Product Name: Clobazam Tablets 10 mg and 20 mg****2. Composition/Information on Ingredients**

C.A.S. No : 22316-47-8
Molecular Formula : $C_{16}H_{13}O_2N_2Cl$
Molecular Weight : 300.74
Chemical Name : 7-Chloro-1-methyl-5-phenyl-1H-1,5 benzodiazepine-2,4(3H,5H)-dione

3. Hazards Identification

Handling should only be performed by personnel trained and familiar with handling of potent active pharmaceutical ingredients Moderate to severe irritant to the skin and eyes.

4. First Aid Measures**Description of First Aid Measures**

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.

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.

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

NOTES TO HEALTH PROFESSIONALS

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.

OVERDOSAGE**Signs and Symptoms of Overdosage**

Overdose and intoxication with benzodiazepines, including clobazam, may lead to CNS depression, associated with drowsiness, confusion and lethargy, possibly progressing to ataxia, respiratory depression, hypotension, and, rarely, coma or death. The risk of a fatal outcome is increased in cases of combined poisoning with other CNS depressants, including alcohol.

Management of Overdosage

The management of clobazam overdose may include gastric lavage and/or administration of activated charcoal, intravenous fluid replenishment, early control of airway and general supportive measures, in addition to monitoring level of consciousness and vital signs. Hypotension can be treated by replenishment with plasma substitutes and, if necessary, with sympathomimetic agents. The efficacy of supplementary

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administration of physostigmine (a cholinergic agent) or of flumazenil (a benzodiazepine antagonist) in clobazam overdose has not been assessed. The administration of flumazenil in cases of benzodiazepine overdose can lead to withdrawal and adverse reactions. Its use in patients with epilepsy is typically not recommended.

5. Emergency Overview

Major Health Hazards: No major health hazards are known

6. Fire Fighting Measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

7. Accidental Release Measures**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, 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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

8. Handling and Storage**Precautions for Safe Handling:**

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Use appropriate ventilation. Avoid generating airborne dust. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions

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of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities**Storage Conditions:****US :** Store at 20°C to 25°C (68°F to 77°F).(USP controlled room temperature).**Europe :** Store below 25°C.**Specific end use(s):** Pharmaceutical drug product**9. Exposure Controls/Personal Protection**

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

10. Physical and Chemical Properties**Appearance:**

10 mg tablets: White to off white, oval shaped uncoated tablets with breakline on one side and “C” and “L” debossed on the other side.

20 mg tablets : White to off white, oval shaped uncoated tablets with breakline on one side and “C” and “L” debossed on the other side.

11. Stability and Reactivity**Reactivity:** No data available**Stability:** Stable under normal conditions of use.**Oxidizing Properties:** No data available**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers**Hazardous Decomposition Products:** None known**12. Toxicological Information****Carcinogenesis, Mutagenesis, Impairment of Fertility**

The carcinogenic potential of clobazam has not been adequately assessed. In a limited study in rats, oral administration of clobazam (4, 20, and 100 mg/kg/day) for 2 years resulted in an increased incidence of thyroid follicular cell adenomas in males at the high dose. Clobazam and the major active metabolite, N-desmethylclobazam, were negative for genotoxicity, based on data from a battery of in vitro (bacteria reverse mutation, mammalian clastogenicity) and in vivo (mouse micronucleus) assays. In a study in which clobazam (50, 350, or 750 mg/kg/day) was orally administered to male and female rats prior to and during mating and continuing in females to gestation day 6, increases in abnormal sperm and pre-implantation loss were observed at the highest dose tested. The no effect level for fertility and early embryonic development

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in rats was associated with plasma exposures (AUC) for clobazam and its major active metabolite, N-desmethyloclobazam, less than those in humans at the maximum recommended human dose of 40 mg/day.

13. Ecological Information

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

14. Disposal Considerations

Dispose of in accordance with prevailing country, federal, state and local regulations.

15. Transport Information

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

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

16. Regulatory Information

California Proposition 65: Not Listed

Inventory - United States TSCA - Sect. 8(b): Present

Australia (AICS): Present

EU EINECS/ELINCS List Not Listed

Additional Information: U.S. Drug Enforcement Agency Controlled Drug Substance, Schedule V

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.