

MATERIAL SAFETY DATA SHEET

Version No: MSDS/CLAM/DP-001

Effective Date: January 25, 2013

CLONAZEPAM TABLETS USP 0.5 mg, 1 mg and 2 mg

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: CLONAZEPAM TABLETS USP 0.5 mg, 1 mg and 2 mg

Marketing Authorisation Holder

Accord Healthcare, Inc.,
1009 Slater Road,
Suite 210-B,
Durham, NC 27703, USA.
Telephone: 1-919-941-7878
Fax- 1-919-941-7881

Manufacturer

Intas Pharmaceuticals Ltd.
Plot No. 457, 458
Village-Matoda,
Bavla Road, Ta. Sanand,
Dist. Ahmedabad-382 210,
Gujarat, India

US Emergency Phone: Call CHEMTREC Day or Night: 1-800-424-9300

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Active: Clonazepam

Inactive: Anhydrous lactose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and starch (corn), with the following colorants: 0.5 mg-FD&C Yellow No. 6 Lake and 1 mg-FD&C Blue No.2 Lake.

SECTION 3 - HAZARDS IDENTIFICATION

Emergency Overview: Reproductive Hazard.

Form: Solid

Adverse Effects: Adverse effects of benzodiazepines may include memory loss, confusion, false sense of well-being, drowsiness, dizziness, weakness, unsteadiness, headache, blurred or double vision, slurred speech, nausea, diarrhea, and constipation. Clonazepam may also cause weight gain, abnormal eye movements, chest congestion, and dry mouth or hypersalivation. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Overdose effects include the adverse effects listed above and fast or slow heartbeat; low blood pressure; troubled breathing; cold, clammy skin; coma; and death.

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Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization, tolerance, and dependence. Withdrawal symptoms may include restlessness, hallucinations, delirium, seizures, fast heartbeat, high blood pressure, flu-like aches, nausea, vomiting, and unsteadiness.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, alcohol or drug abuse, laucoma, myasthenia gravis, lung disease, sleep apnea, kidney or liver impairment, porphyria, seizure disorders, and mental disorders such as depression.

Cross Sensitivity: Individuals sensitive to one of the benzodiazepines may be sensitive to this material also.

Target Organs: Central nervous system.

SECTION 4 - EMERGENCY & FIRST AID MEASURES

General First Aid Procedures: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

Inhalation: May cause irritation. Remove to fresh air.

Eye contact: May cause irritation. Flush with copious quantities of water.

Skin contact: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water. This material is rapidly and well absorbed from the gastrointestinal tract.

Note to Physicians

Overdose Treatment: Treatment of benzodiazepine overdose should be symptomatic and supportive and may include the following:

1. Do not induce vomiting.
2. Administer activated charcoal as a slurry.
3. Monitor vital signs, manage airway, and provide assisted ventilation if needed.
4. Infuse 10 - 20 mL/kg isotonic fluid to control hypotension. If persistent, treat with intravenous administration of a vasopressor such as dopamine or norepinephrine.

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5. Flumazenil, a benzodiazepine agonist/antagonist, has been administered intravenously to reverse coma and respiratory depression in cases of severe poisoning. Flumazenil use is not recommended in cases where seizures are likely or there is serious cyclic antidepressant poisoning.

6. Forced diuresis and hemodialysis are ineffective.

7. Manage withdrawal symptoms initially with phenobarbital or the benzodiazepine, then decrease dose by about 10% per day for ten days. [Meditext 2009]

SECTION 5 - FIRE FIGHTING MEASURES

Extinguishing Media:

Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards:

This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures:

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Spill Response:

Wear approved respiratory protection, chemically compatible gloves, and protective clothing. Wipe up spillage or collect spillage using a high-efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labeled container for disposal. Wash spill site.

SECTION 7 - HANDLING AND STORAGE

Handling

Technical measures : local exhaust ventilation necessary, avoid dust formation; consider dust explosion hazard

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Storage

- keep containers tightly closed
- room temperature
- store in dry place.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory protection:

Required when dusts are generated.

Eye protection:

Safety glasses or goggles.

Hand protection:

Required.

Industrial hygiene:

This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Description of Tablets:

0.5 mg tablet: orange, round, flat faced, beveled edge, scored, debossed with "1" and "2" on one side and plain on other.

1 mg tablet: blue, round, flat faced, beveled edge, debossed with "C 1" on one side and plain on the other.

2 mg tablet: white to off white, round, flat faced, beveled edge tablets debossed with "C 2" on one side and plain on the other.

SECTION 10 - STABILITY AND REACTIVITY

Stability: Yes

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Polymerization: No

Conditions to avoid: Light, heat, and sources of ignition

Decomposition Products: When heated to decomposition, material emits toxic fumes of HCl and NOx. Emits toxic fumes under fire conditions.

SECTION 11 - TOXICOLOGY INFORMATION

Acute toxicity: LD₅₀ >15 grams/kg (oral, rat)
LD₅₀ 2 grams/kg (oral, mouse)

Listed as a Carcinogen by: NTP: No, IARC: No, OSHA: No

Other Carcinogenicity Data: No

Mutagenicity: Clonazepam was not mutagenic in vitro in the host-mediated assay, the B. subtilis (Rec) assay, the E. coli (pol and uvr) assay, and the Ames assay with and without activation.

Reproductive and Developmental Effects: Results were mixed in a meta-analysis of studies that tracked the occurrence of major malformations in infants of mothers who used a benzodiazepine in early pregnancy. There have been reports of newborns exhibiting flaccidity, breathing and feeding problems, and hypothermia after maternal use of benzodiazepines in late pregnancy, and withdrawal symptoms, e.g. tremor and irritability, have been seen in newborns exposed to benzodiazepines in utero. In rabbits given oral doses of 0.2 to 10 mg/kg/day during gestation, there was a non-doserelated incidence of cleft palate, open eyelid, fused sternebrae, and limb defects. In mice and rats, oral doses up to 15 and 40 mg/kg/day, respectively, did not cause birth defects.

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Ecological Information: Moderately toxic for planktonic crustaceans. Barely toxic to fish. Not inherently biodegradable.

SECTION 13 - DISPOSAL INFORMATION

Dispose of waste in accordance with all applicable Federal, State, and local laws. Additionally, because this is a controlled substance, notify local DEA office for appropriate disposal procedures.

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SECTION 14 - TRANSPORTATION INFORMATION

This product is not subject to the regulations for the safe transport of hazardous chemicals.

DOT: Not regulated

TDG: Not regulated

IATA: Not regulated

IMDG: Not regulated

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: DEA Schedule IV Controlled Substance

International Regulatory Information: EINECS # 216-596-2
Hazard Code: Xn
Risk Phrases: R22, R40

SECTION 16 - OTHER DATA

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall INTAS be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if INTAS has been advised of the possibility of such damages.