SECTION 01 – IDENTIFICATION

Manufactured By:
Gland Pharma Limited
D.P. Pally, Dundigal Post,
Hyderabad – 500 043, India

Manufactured For:
BPI Labs, LLC
6911 Bryan Dairy Road
Largo, FL 33777

Telephone: 1-727-471-0850
Emergency Phone: 1-727-471-0850

Product Name: Zoledronic Acid Injection, 4 mg / 5 mL (0.8 mg / mL)

Synonyms: Not Applicable.

Therapeutic Use: Zoledronic Acid Injection is a bisphosphonate indicated for the treatment of hypercalcemia of malignancy, and for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy.

Restrictions on Use: Zoledronic Acid Injection is contraindicated in patients with hypersensitivity to Zoledronic Acid or any components of Zoledronic Acid Injection. In addition, patients being treated with Zoledronic Acid Injection should not take Reclast or other bisphosphonates.

Description: Zoledronic acid injection contains zoledronic acid (white crystalline powder), a bisphosphoric acid which is an inhibitor of oesteoclastic bone resorption. Zoledronic Acid Injection is available in 5 mL single-use vial as a sterile liquid concentrate solution for intravenous infusion. Each 5 mL concentrate vial contains 4.264 mg zoledronic acid monohydrate, corresponding to 4 mg zoledronic acid on an anhydrous basis, 220 mg of mannitol, USP, water for injection, and 24 mg of sodium citrate dihydrate, USP.

SECTION 02 – HAZARD(S) IDENTIFICATION

Hazard Statement: Suspected of damaging fertility or the unborn child.
Harmful is swallowed.
May cause respiratory irritation.
May Cause harm to breast-fed children

Precautionary Statement: Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust / fume / gas / mist / vapors / spray.

Signal Word: Warning.

Eye: Contact with eyes may cause irritation.

Skin: May cause skin irritation.

Inhalation: May cause irritation of respiratory tract.

Ingestion: May cause irritation.

SECTION 03 – COMPOSITION AND INFORMATION ON INGREDIENTS

Ingredients	CAS Number	Amount
Zoledronic Acid on Anhydrous Basis	118072-93-8	4 mg
Inactive Ingredients	**CAS Number**	**Amount**
Mannitol, USP	69-65-8	220 mg
Sodium Citrate Dihydrate, USP	6132-04-3	24 mg
Water for Injection	7732-18-5	qs

SECTION 04 – FIRST AID MEASURES

Eyes: If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persist, notify medical personnel and supervisor.

Skin: Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persist, notify medical personnel and supervisor.

Inhalation: Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

Ingestion: Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

SECTION 05 – FIRE FIGHTING MEASURES

General Hazard: Not considered to be a fire hazard.

Fire Fighting Instructions: Wear full protective clothing and a self-contained breathing apparatus with a full face piece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

Extinguisher to Use: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Flash Point: Not available.

Auto-ignition: Not established.

Flammability Limits: Not considered to be a fire hazard. No explosivity data available. High concentrations of finely divided airborne organic particles can potentially explode of ignited.

Hazardous Combustion Products: Not known.

Minimum Explosive Concentration for Dust / Vapor: Not known.

SECTION 06 – ACCIDENTAL RELEASE MEASURES

Protective Equipment: Personnel involved in clean-up should wear appropriate equipment (see section 08). Minimize exposure.

Occupational Spill: If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment. Area should be adequately ventilated. Do not breathe dust. Do not empty into drains. Avoid release to the environment.

Clean-up – Large Spill: Review Sections 02 and 08 proceeding with the clean up. Do not raise dust. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto

SECTION 06 – ACCIDENTAL RELEASE MEASURES (CONTINUATION)

spill absorbents. Place spill materials into leak-proof container suitable for disposal in accordance with applicable waste disposal regulations. Decontaminate the area twice. Large spills may be subject to EPA/CERCLA Section 103 Release Report Requirements.

SECTION 07 – HANDLING AND STORAGE

General Handling: Follow recommendations for handling potent cytoxic pharmaceutical agents (i.e., use of engineering controls and / or other personal protective equipment if needed). Avoid breathing dust. Wash thoroughly after handling.

Storage: Store vials as directed in package insert. Keep vials closed when not in use.

Incompatible Materials: None Known.

Temperature Range: Store at 25°C (77°F); excursions permitted to 15°C - 30°C (59°F - 86°F) [See USP Controlled Room Temperature].

SECTION 08 – EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA's Permissible Exposure Limits (PELs): None established.

ACGIH Threshold Limit Values (TLVs): Data not available.

Engineering Controls: Open handling should not be performed when handling potent substances or substances of unknown toxicity. Control exposures to below the OEL (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.

Personal Protective Equipment: Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling. Refer to below recommended protection.

Eye Protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin Protection: Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Hand Protection: Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Respiratory Protection: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters or combination filters should provide ancillary protection based on the known or foreseeable limitations of existing engineering controls. Use a positive-pressure air supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known, or in any other circumstances where air purifying respirators may not provide adequate protection.

SECTION 09 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Form:	Sterile Liquid Concentrate Solution.
Color:	Clear, colorless
Odor:	Odorless.
Molecular Weight:	290.1 g/mol
Molecular Formula:	$C_5H_{10}N_2O_7P_2$
pH:	5.7 – 6.7
Melting Point:	Not available.
Vapor Pressure:	Not available.
Water Solubility:	Highly soluble.
Solvent Solubility:	Not available.

SECTION 10 – STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions and temperature.
Reactivity:	None Known.
Conditions to Avoid:	Protect from light and temperatures exceeding 86 ºF (30ºC). Avoid extreme temperatures. Avoid direct sunlight.
Incompatibilities:	None Known.
Hazardous Polymerization:	Will not occur.
Hazardous Decomposition Products:	Carbon oxides, nitrogen oxides.
Oxidizing Properties:	None Known.
Explosive Properties:	None Known.

SECTION 11 – TOXICOLOGICAL INFORMATION

Acute Toxicity: Eye, skin and respiratory irritation may occur. Moderately toxic by ingestion.

Additional Exposure Precautions: Not applicable.

Exposure Limits:

Compound	Issuer	Type	OEL
Zoledronic Acid	OSHA	PEL	NE
	ACGIH	TLV	NE
	--------	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	--------	STEL	NE
Citric Acid	OSHA	PEL	NE
	ACGIH	TLV	NE
	--------	STEL	NE

PEL: Permissible Exposure Limit (OSHA).
TLV: Threshold Limit Value.
STEL: Short Term Exposure Limit.
NE: Not Established.

Acute Effects: Eye, skin and respiratory irritation may occur. Moderately toxic by ingestion.

Chronic Effects: Hypersensitivity reactions ranging from mild to severe may occur.

SECTION 12 – ECOLOGICAL INFORMATION

Signs & Symptoms of Exposure: Common adverse effects include nausea, vomiting, gastro intestinal irritation, fatigue, decreased red blood cell count (anemia), constipation fever, shortness of breath (dyspnea), and bone pain.

Acute Toxicity:

Component	Type	Route	Species	Dosage
Zoledronic Acid	Minimum Lethal Dose	Intravenous	Mouse	>10 mg/Kg
Zoledronic Acid	Minimum Lethal Dose	Intravenous	Rat	>0.6 mg/kg

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal Procedure: Dispose of wastes in accordance to prescribed federal, state, and local guidelines (i.e. appropriately permitted chemical waste incinerator).

SECTION 14 – TRANSPORT INFORMATION

Proper Shipping Name: Zoledronic Acid Injection, 4 mg / 5 mL (0.8 mg / mL)

General Shipping Instructions: Non-regulated.

SECTION 15 – REGULATORY INFORMATION

No Data Available.

Labeling on Container to Include: Product Name, Batch Number, Expiry Date, Storage Conditions, Company Name and Address.

SECTION 16 – OTHER INFORMATION

Disclaimer: BPI Labs, LLC. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.