

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

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Material	Doxercalciferol Injection 4 mcg/2 mL multi-dose vial
Manufacturer	Gland Pharma Limited D. P. Pally, Hyderabad - 500 043 INDIA
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

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Fire and Explosion	Expected to be non-combustible.
Health	Doxercalciferol should not be given to patients with a tendency towards hypercalcemia or current evidence of vitamin D toxicity. Doxercalciferol injection is contraindicated in patients with previous hypersensitivity to doxercalciferol or any of its ingredients
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	CAS
Doxercalciferol	54573-75-0

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Get medical aid immediately. Wash mouth out with water.
Inhalation	Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical aid.

Skin Contact

Get medical aid. Flush skin with plenty of water and soap for at least 15 minutes while removing contaminated clothing and shoes. Get medical aid if irritation develops and persists.

Eye Contact

Flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid.

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

Administration of doxercalciferol to patients in excess doses can cause hypercalcemia, hypercalciuria, hyperphosphatemia, and over-suppression of PTH secretion leading in certain cases to adynamic bone disease. High intake of calcium and phosphate concomitant with doxercalciferol may lead to similar abnormalities. High levels of calcium in the dialysate bath may contribute to hypercalcemia.

General treatment of hypercalcemia (greater than 1 mg/dL above the upper limit of the normal range) consists of immediate suspension of doxercalciferol therapy, institution of a low calcium diet, and withdrawal of calcium supplements. Serum calcium levels should be determined at least weekly until normocalcemia ensues. Hypercalcemia usually resolves in 2 to 7 days. When serum calcium levels have returned to within normal limits, doxercalciferol therapy may be reinstated at a dose that is at least 1 mcg lower than prior therapy. Serum calcium levels should be obtained weekly after all dosage changes and during subsequent dosage titration. Persistent or markedly elevated serum calcium levels may be corrected by dialysis against a reduced calcium or calcium-free dialysate.

The treatment of acute accidental overdosage of doxercalciferol should consist of general supportive measures. Serial serum electrolyte determinations (especially calcium), rate of urinary calcium excretion, and assessment of electrocardiographic abnormalities due to hypercalcemia should be obtained. Such monitoring is critical in patients receiving digitalis. Discontinuation of supplemental calcium and institution of a low calcium diet are also indicated in accidental overdosage. If persistent and markedly elevated serum calcium levels occur, treatment with standard medical care should be followed, as needed. Based on similarities between doxercalciferol and its active metabolite, $1\alpha,25\text{-(OH)}_2\text{D}_2$, it is expected that doxercalciferol is not removed from the blood by dialysis.

Section 5: Fire-Fighting Measures**Section 5, Fire-fighting measures****Fire and Explosion Hazards**

Water. Carbon dioxide (CO₂). Dry chemical.

Extinguishing Media

Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.

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.

Section 6: Accidental Release Measures

Section 6, Accidental release measures**Personal Precautions**

Wear suitable protective clothing, gloves and eye/face protection. Do not breathe dust.

Environmental Precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods

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.

Section 7: Handling and Storage

Section 7, Handling and storage**Handling**

Avoid contact with eyes, skin, and clothing. Wear personal protective equipment.

Storage

Store unopened multi-dose vials at 25°C (77°F): excursions permitted to 15 to 30°C (59 to 86°F) [see USP controlled room temperature]
Store opened multi-dose vials at 2 to 8°C (36 to 46°F)

Protect from light.

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

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

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties**Physical Form**

Doxercalciferol Injection is supplied in multi-dose amber glass vials containing 4 mcg doxercalciferol in 2 mL of solution. The closure consists of a fluorocarbon-coated bromobutyl stopper, with an aluminum seal and an orange plastic flip-off cap.

NDC 68180-718-01	4 mcg/2 mL multi-dose vial
NDC 68180-718-52	4 mcg/2 mL vials in packages of 50
NDC 68180-718-12	4 mcg/2 mL vials in packages of 10

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate the carcinogenic potential of doxercalciferol have not been conducted. No evidence of genetic toxicity was observed in an *in vitro* bacterial mutagenicity assay (Ames test) or a mouse lymphoma gene mutation assay. Doxercalciferol caused structural chromatid and chromosome aberrations in an *in vitro* human lymphocyte clastogenicity assay with metabolic activation. However, doxercalciferol was negative in an *in vivo* mouse micronucleus clastogenicity assay. Doxercalciferol had no effect on male or female fertility in rats at oral doses up to 2.5 mcg/kg/day (approximately 3 times the maximum recommended human oral dose of 60 mcg/wk based on mcg/m² body surface area).

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

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IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 16, Other 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. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.