



Product Name: Carboplatin Injection (Aqueous Solution)

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name Getwell Pharmaceuticals
And Address 474, Udyog Vihar, Phase-V,
Gurgaon - 122 016, Haryana, INDIA

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Product Name Carboplatin Injection (Aqueous Solution)

Synonyms Carbotin , 1,1 cyclobutanedicarboxylic acid platinum complex, CBDCA

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Carboplatin
Chemical Formula C₆H₁₂N₂O₄ Pt

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Carboplatin	1	41575-94-4	NA
Water	99	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview In clinical use, this material is used as an antineoplastic agent. Carboplatin is toxic if injected or swallowed and may cause damage to the kidneys, bone marrow, blood, liver, nervous and gastrointestinal system. Harmful to the fetus. May cause allergic skin and/or respiratory reactions.

Occupational Exposure Potential Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Occupational exposure may cause irritation to the skin, eyes, and respiratory tract.

Signs and Symptoms Effects of overexposure may include decreased blood platelets, granulocytes and white blood cells, fever, anemia, nausea, abdominal pain, diarrhea, constipation, peripheral neuropathy, visual disturbances, abnormal renal and liver function tests, rash, hives, redness itching, bronchospasms and decreased blood pressure.

Medical Conditions Aggravated by Exposure Kidney, bone marrow, blood, liver and nervous system disorders may be aggravated by exposure to this material. Avoid exposure during pregnancy.

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4. FIRST AID MEASURES

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability: Non-flammable

Fire & Explosion Hazard: None

Extinguishing Media: Use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Immediate cleanup of any spill is recommended. Collect spilled liquid using techniques that minimize aerosol generation. Clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling Carboplatin is cytotoxic. Work practices and controls to minimize occupational exposure should be followed. Wash hands thoroughly after handling.

Storage No special storage required for hazard control. Refer to the product insert for product storage information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure Limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Platinum (soluble)	8 hr TWA: 2 mcg/m ³	8 hr TWA: 2 mcg/m ³	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION CONTINUED

Respiratory Protection	Respiratory protection is not needed during normal product use.
Skin Protection	Glove use, latex, nitrile, or rubber, is recommended.
Eye Protection	Eye protection is recommended during the handling of this product.
Engineering Controls	Engineering controls are not needed during normal product use conditions. Cytotoxic agents should be prepared in a designated area where spills are easily managed and airflow is directed away from the preparer's breathing zone.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear, colorless liquid
Odor	Not Determined
Boiling Point	Approximately that of water (100 °C, 212 °F)
Freezing Point	Approximately that of water (0 °C, 32 °F)
Vapor Pressure	Approximately that of water (17.5 mm Hg at 20 °C)
Vapor Density (Air=1)	Not Applicable
Evaporation Rate	Not Applicable
Bulk Density	Not Determined
Specific Gravity	Approximately that of water (1.0)
pH	5 - 7

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	May react with strong oxidizing agents. Aluminum can react with carboplatin causing precipitate formation and loss of potency.
Hazardous Decomposition Products	Oxides of carbon and nitrogen.
Hazardous Polymerization	Will not occur.
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11. TOXICOLOGICAL INFORMATION

Acute Toxicity – Oral:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Carboplatin	100	LD50	343	mg/kg	Rats

LD50 is the oral dosage that produces 50% mortality.
Product contains approximately 1% Carboplatin.

Acute Toxicity – Intravenous

Ingredient(s)	Percent	Test Type	Value	Units	Species
Carboplatin	100	LD50	61 89	mg/kg	Rats Mice

LD50 (iv) is the intravenous dosage that produces 50% mortality.
Product contains approximately 1% Carboplatin.

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11. TOXICOLOGICAL INFORMATION CONTINUED

Carcinogenic Potential	Compounds with similar cytotoxic mechanisms of action and mutagenic activity have been reported to be carcinogenic. Carboplatin is not listed as carcinogenic by NTP, IARC or OSHA.
Mutagenicity	Mutagenic in both in vitro and in vivo mutagenesis assays and the mouse lymphoma assay.
Reproductive Effects	Carboplatin is classified: Pregnancy Category D (Positive evidence of risk). Doses of 24 mg/kg/day administered to rats between the sixth and ninth days of pregnancy were associated with specific developmental abnormalities of the central nervous system, musculoskeletal system, and body wall. Carboplatin is listed as a Proposition 65 developmental toxin by the State of California.
Target Organ Effects	Carboplatin poses a potential hazard to the kidneys, bone marrow, blood, liver, and nervous and gastrointestinal system.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity Not Available

13. DISPOSAL CONSIDERATIONS:

Waste Disposal	Disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

DOT Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status	Not Regulated
CERCLA Status	Not Regulated
SARA Status	Not Regulated
RCRA Status	Not Regulated

PROP 65 (Calif.) Carboplatin is listed as a developmental toxicant.

Notes: TSCA Toxic Substance Control Act
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
SARA Superfund Amendments and Reauthorization Act
RCRA US EPA, Resource Conservation and Recovery Act
Prop 65, California Proposition 65

16. OTHER INFORMATION

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