

Cistor® IV Injection

Cisplatin USP Injection

DESCRIPTION

Cistor® IV Injection is a preparation of Cisplatin. Cisplatin is a heavy metal complex containing a central atom of platinum surrounded by two chloride atoms and two ammonia molecules in the cis position. Due to its unique chemical structure, the chlorine atoms of cisplatin are more subject to chemical displacement reactions by nucleophiles, such as water or sulfhydryl groups, than to enzyme-catalyzed metabolism. At physiological pH in the presence of 0.1M NaCl, the predominant molecular species are cisplatin and monohydroxymonochloro cis-diammine platinum (II) in nearly equal concentrations. The latter, combined with the possible direct displacement of the chlorine atoms by sulfhydryl groups of amino acids or proteins, accounts for the instability of cisplatin in biological matrices.

INDICATIONS

- **Metastatic Testicular Tumors:** In established combination therapy with other approved chemotherapeutic agents in patients with metastatic testicular tumors who have already received appropriate surgical and/or radiotherapeutic procedures.
- **Metastatic Ovarian Tumors:** In established combination therapy with other approved chemotherapeutic agents in patients with metastatic ovarian tumors who have already received appropriate surgical and/or radiotherapeutic procedures. An established combination consists of Cisplatin Injection and cyclophosphamide. Cisplatin Injection, as a single agent, is indicated as secondary therapy in patients with metastatic ovarian tumors refractory to standard chemotherapy who have not previously received Cisplatin Injection therapy.
- **Advanced Bladder Cancer:** Cisplatin Injection is indicated as a single agent for patients with transitional cell bladder cancer which is no longer amenable to local treatments, such as surgery and/or radiotherapy.

DOSAGE AND ADMINISTRATION

- **Metastatic Testicular Tumors:** The usual Cisplatin Injection dose for the treatment of testicular cancer in combination with other approved chemotherapeutic agents is 20 mg/m² IV daily for 5 days per cycle.
- **Metastatic Ovarian Tumors:** The usual Cisplatin Injection dose for the treatment of metastatic ovarian tumors in combination with cyclophosphamide is 75 to 100 mg/m² IV per cycle once every four weeks (DAY 1). The dose of cyclophosphamide when used in combination with Cisplatin Injection is 600 mg/m² IV once every 4 weeks (DAY 1). For directions for the administration of cyclophosphamide, refer to the cyclophosphamide package insert. In combination therapy, Cisplatin Injection and cyclophosphamide are administered sequentially. As a single agent, Cisplatin Injection should be administered at a dose of 100 mg/m² IV per cycle once every four weeks.

- **Advanced Bladder Cancer:** Cisplatin Injection should be administered as a single agent at a dose of 50 to 70 mg/m² IV per cycle once every 3 to 4 weeks depending on the extent of prior exposure to radiation therapy and/or prior chemotherapy. For heavily pretreated patients an initial dose of 50 mg/m² per cycle repeated every 4 weeks is recommended.

CONTRAINDICATIONS

- History of hypersensitivity
- Preexisting renal impairment
- Myelosuppressed patients
- Hearing impairment

SIDE EFFECTS

- Nephrotoxicity
- Ototoxicity
- Hematologic: Leukopenia, thrombocytopenia, Anaemia
- Gastrointestinal: Nausea, vomiting, diarrhea, anorexia

WARNING AND PRECAUTION

Cisplatin Injection should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents. Appropriate management of therapy and complications is possible only when adequate diagnostic and treatment facilities are readily available. Peripheral blood counts should be monitored weekly. Liver function should be monitored periodically. Neurologic examination should also be performed regularly.

USE IN PREGNANCY AND LACTATION

Pregnancy Category D. Cisplatin has been reported to be found in human milk; patients receiving cisplatin should not breast-feed.

PHARMACEUTICAL PRECAUTION

Do not store in wet place. Keep away from light. Keep out of reach of children.

PACKAGING

Cistor® 10 IV Injection: Each box contains 1 vial of Cisplatin 10 mg/10 mL injection.

Cistor® 50 IV Injection: Each box contains 1 vial of Cisplatin 50 mg/50 mL injection.

SK+F ONCOLOGY

Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
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