

## Abridged Prescribing Information

### STRICARB™ (Carboplatin)

**Composition:** STRICARB™ (Carboplatin inj.) is supplied as a sterile, pyrogen free, 10 mg/ml (150 mg/15ml and 450 mg/45ml) aqueous solution of Carboplatin. **Indications:** Ovarian carcinoma (including second-line palliative treatment in patient who has previously received cisplatin- containing regimens), head & neck cancer, small cell lung cancer and cervical cancer. **Dosage and Administration:** The drug is for Intravenous (IV) use only and has to be administered by IV infusion over a period of at least 15 minutes. Two standards for dosing Carboplatin are renal function and Body surface area (BSA). **Single-agent therapy:** An initial single dose of 360 to 400 mg/m<sup>2</sup> is recommended. Combination chemotherapy: In combination with other cytotoxic drugs, Carboplatin is recommended at the initial dosage of 300 mg/m<sup>2</sup>. **Special populations:** a) **Pregnancy:** Carboplatin may cause harm to the fetus when administered to pregnant women. The drug should be used during pregnancy only in life-threatening situations. b) **Lactation:** It is not clearly established whether Carboplatin or its platinum-containing metabolites are distributed into human milk. However, because of the potential for serious adverse reactions in infants should the drug pass into the milk; nursing should be discontinued during therapy. c) **Geriatric:** Reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Because renal function is often decreased in the elderly, renal function should be considered in the selection of Carboplatin dosage. **Contraindications:** Treatment with Carboplatin is contraindicated in the following conditions: In patients with a history of hypersensitivity reactions to Carboplatin or other platinum-containing compounds (e.g., cisplatin), in the presence of severe renal impairment, in the presence of severe bone marrow depression, in the presence of substantial bleeding. **Warnings and Precautions:** The administration of carboplatin should be carried out under the supervision of physicians fully trained in the use of cytotoxic drugs. A close monitoring for toxicity is mandatory, particularly in the case of administration of high drug dosages. Carboplatin is a highly toxic drug with a narrow therapeutic index and a therapeutic effect is unlikely to occur without some evidence of toxicity. **Adverse Reactions:** Neoplasms benign, malignant and unspecified, blood and lymphatic system disorders, metabolism and nutrition disorders, nervous system disorders, eye disorders, ear and labyrinth disorders. **Storage:** Store at 20°-25°C. Protect from light & free from contact with aluminum. Keep out of the reach of children. Carboplatin injection multidose vial maintain microbial, chemical and physical stability for up to 14 days at 25°C following multiple needle entries.

Dated: 27<sup>th</sup> June 2017

For more details and information, please refer the pack insert or full prescribing information.