# Carboplatin Injection

## PRODUCT INFORMATION

**WARNINGS**

- **Hypersensitivity**
- **Carcinogenesis, Mutagenesis, Impairment of Fertility**

**DESCRIPTION**

Carboplatin is a platinum analog. It is a synovial derivative that contains a coordinated water molecule and a nitrogen-containing ligand. Carboplatin is stable as a free drug, and the major metabolites are the mono- and di-carboxylic acids. Carboplatin is used in the treatment of various cancer types, including ovarian cancer and non-small cell lung cancer.

**INDICATIONS**

- Ovarian cancer
- Non-small cell lung cancer

**CONTRAINDICATIONS**

- Hypersensitivity to carboplatin or any component of the formulation
- Uncontrolled infection

**PRECAUTIONS**

- Monitor for myelosuppression
- Use with caution in patients with impaired renal function

## DOSAGE AND ADMINISTRATION

- **Parenteral**
- **Dosage**

  - Calculate the dose based on body surface area (BSA) and the desired AUC or area under the curve.

## ADVERSE REACTIONS

- **Common**
  - Myelosuppression
  - Nausea
  - Vomiting

## DRUG INTERACTIONS

- **Interactions with Other Drugs**
- **Interactions with Food**

## PATIENT INFORMATION

- **Precautions**
- **Side Effects**

## STORAGE

Store at controlled room temperature.

## TABLES

### Table 1: Parenteral Solutions

<table>
<thead>
<tr>
<th>Solution</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution A</td>
<td>50 mg/mL</td>
</tr>
<tr>
<td>Solution B</td>
<td>100 mg/mL</td>
</tr>
</tbody>
</table>

**Note:** Solutions A and B are used to prepare the final dilutions for intra-arterial and intravenous administration. The final concentration should be 1 mg/mL or 2 mg/mL for optimal drug delivery and patient safety.

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**Note:** The information provided is a summary of the package insert for Carboplatin Injection. For detailed information, please refer to the complete package insert provided by the manufacturer.
The most serious side effects of carboplatin are reported in patients receiving cancer chemotherapy with multiple drugs. It is not always possible to tell whether cells as well as cancer cells. For example, the occurrence of another cancer (secondary malignancy) has been

Carboplatin may cause unwanted effects, particularly because carboplatin interferes with the growth of normal with adults or children who have received oral polio vaccine since they can pass the polio virus to you. You should avoid contact with adults and children who have infections, and tell your doctor right away if you show

Carboplatin may harm your developing fetus or breastfeeding baby. If you are a woman of childbearing age, you

What should I avoid while taking carboplatin?

• If you are breastfeeding, since nursing infants may be exposed to carboplatin in this way;
• If you are allergic to carboplatin or other platinum-containing products;

Be sure to inform your doctor:

Discuss the benefits and risks of carboplatin with your doctor before beginning treatment.

Before and after carboplatin treatment, your doctor may give you medication to lessen the nausea and vomiting by dripping the medicine slowly and directly into a vein (intravenous infusion) for 15 minutes or longer. Your doctor

Only a professional experienced in the use of cancer drugs should give you this medication. Carboplatin is given

How is carboplatin used?

• have a weakened blood-forming system (bone marrow depression) or significant bleeding;
• Treatment with carboplatin is not recommended if you:

Who should not take carboplatin?

What is cancer?

A tumor is a mass of tissue—rapidly multiplying cells, particularly cancer cells. If the tumor invades surrounding healthy body tissue it is known as a malignant tumor. A malignant tumor can spread (metastasize) from its original location to other parts of the body.

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What is cancer?
The most serious side effects of carboplatin are:

- Effects may be serious, you will need close medical supervision during treatment with carboplatin.
- Carboplatin is associated with increased risk of secondary malignancies.

What are the possible side effects of carboplatin?

- Increased risk of secondary malignancies, including leukemia and non-Hodgkin's lymphoma.
- Nausea, vomiting, diarrhea, loss of appetite, hair loss, numbness, tingling, burning, or pain in the hands and feet.
- Other less serious side effects may include:
  - loss of hearing or ringing in the ears;
  - loss of counterclockwise movement of the fingers or toes;
  - fever, symptoms associated with infection such as cough, fever, and/or chills.

What should I avoid while taking carboplatin?

- You should avoid contact with adults and children who have infections, and tell your doctor right away if you show any signs of infection such as cough, fever, and/or chills. Also, while you are being treated with carboplatin or after you stop treatment, first check with your doctor before receiving any vaccinations, including flu shots.

What should you tell your doctor before starting treatment with carboplatin?

- Discuss the benefits and risks of carboplatin with your doctor before beginning treatment.
- Let your doctor know if you:
  - are pregnant, intend to become pregnant, or are breastfeeding a baby.
  - have a weakened blood-forming system (bone marrow depression) or significant bleeding.
  - are allergic to carboplatin or other platinum-containing products;
  - have kidney or liver disease;
  - have a history of infection;
  - have any blood disorders;
  - are receiving other medications that can interact with carboplatin.

How is carboplatin used?

- Carboplatin may be given alone or with other drugs. Treatment is usually repeated every four weeks for a number of cycles. Your doctor will determine the dose of carboplatin for you based on your weight, height, and kidney function. Carboplatin may be given in an outpatient setting or in a hospital setting.

Additional information:

- Carboplatin is a medicine that is used to treat cancer of the ovaries. It acts by interfering with the division of rapidly multiplying cells, particularly cancer cells.

Before and after carboplatin treatment, your doctor may give you medication to lessen the nausea and vomiting associated with carboplatin treatment. The most common are nausea, vomiting, diarrhea, loss of appetite, hair loss, numbness, tingling, burning, or pain in the hands and feet.

Of the less serious side effects, some are troublesome.

Contact your doctor right away if you experience any of these effects, or notice effects that worry you or are troublesome.

- loss of hearing or ringing in the ears;
- loss of counterclockwise movement of the fingers or toes;
- fever, symptoms associated with infection such as cough, fever, and/or chills;

- Unusual bruising or bleeding, including black tarry stools or blood in the urine.

Discuss the benefits and risks of carboplatin with your doctor before beginning treatment.

The summary can replace careful discussion with your doctor. Remember, no written summary can replace careful discussion with your doctor. You may want to read it and discuss it with your doctor. It does not list all of the benefits and risks of carboplatin. Your doctor can tell you what to expect during carboplatin treatment, the most common are nausea, vomiting, diarrhea, loss of appetite, hair loss, numbness, tingling, burning, or pain in the hands and feet.

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/s/

JOHN F GRACE
03/14/2012
for Wm Peter Rickman