**WARNING**

Carboplatin Injection should be administered under the supervision of a qualified physician who is experienced in the use of cancer chemotherapeutic agents. Therapy and/or complications is possible only when adequate diagnostic facilities are readily available.

**DESCRIPTION**

Carboplatin Injection is supplied as a sterile, pyrogen-free solution available in 10 mg/mL multiple dose vials containing 50 mg, 50 mg/mL, or 100 mg/mL multiple dose vials containing 100 mg or 150 mg. The dose is given by intravenous injection by infusion to patients with impaired renal function. Carboplatin Injection is a platinum coordination compound. The chemical name for carboplatin is platinum (II) cyclobutane-dicarboxylato-n(3)-oxygen (2-)-o,0'-(diamine-N,N-di-n-butyl). It has the following structural formula:

![Chemical structure of carboplatin](https://example.com/structure.png)

### Carboplatin Injection

**Indications**

- **Indications for Initial Treatment of Ovarian Cancer**
  - Carboplatin Injection is indicated for the initial treatment of ovarian cancer in patients who have received no prior chemotherapy and who have not been previously treated with cyclophosphamide.

**CONTRAINdications**

- Carboplatin Injection is contraindicated in patients who have been previously treated with cyclophosphamide, have not been established (see CLINICAL STUDIES and ADVERSE REACTIONS).
- Carboplatin Injection may cause fetal harm when administered to pregnant women. It is not known whether carboplatin is excreted in human milk. A decision should be made whether to discontinue the drug or to discontinue nursing. When the latter is chosen, replacement of milk by an adequate artificial feeding should be advised to avoid becoming pregnant.

**Adverse Reactions**

- Injection site reactions (erythema, induration, and pain) have been observed. These reactions are usually mild and rarely require discontinuation of therapy. They may be exacerbated in patients with impaired renal function.

**Precautions**

- Carboplatin Injection should be administered only by health care professionals who are experienced in the management of patients receiving cytotoxic agents.

**Clinical Studies**

- Carboplatin Injection is effective in the treatment of ovarian cancer. The overall response rate in the first-line setting is approximately 30% to 40%.

**Adverse Events in Patients with Advanced Ovarian Cancer: Swog Study (Continued)**

- **Bone marrow suppression**
  - Neutropenia, thrombocytopenia, and anemia are dose-dependent and are the dose-limiting toxicity. Bone marrow suppression is increased in patients older than 65 years and in patients who have received previous chemotherapy.

**ADVERSE REACTIONS**

- **Injection site reactions**
  - Redness, induration, and pain are common and usually mild. They may be exacerbated in patients with impaired renal function.

**CLINICAL STUDIES**

- Carboplatin Injection is effective in the treatment of ovarian cancer. The overall response rate in the first-line setting is approximately 30% to 40%.

**NURsING CONSIDERATIONS**

- Carboplatin Injection is contraindicated in patients who have been previously treated with cyclophosphamide, have not been established (see CLINICAL STUDIES and ADVERSE REACTIONS).
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**Drug Interactions**

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**Liver Function**

- Carboplatin Injection is contraindicated in patients who have been previously treated with cyclophosphamide, have not been established (see CLINICAL STUDIES and ADVERSE REACTIONS).
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**Pediatric Use**

- Carboplatin Injection is contraindicated in patients who have been previously treated with cyclophosphamide, have not been established (see CLINICAL STUDIES and ADVERSE REACTIONS).
- Carboplatin Injection may cause fetal harm when administered to pregnant women. It is not known whether carboplatin is excreted in human milk. A decision should be made whether to discontinue the drug or to discontinue nursing. When the latter is chosen, replacement of milk by an adequate artificial feeding should be advised to avoid becoming pregnant.

**Gynecological Use**

- Carboplatin Injection is contraindicated in patients who have been previously treated with cyclophosphamide, have not been established (see CLINICAL STUDIES and ADVERSE REACTIONS).
- Carboplatin Injection may cause fetal harm when administered to pregnant women. It is not known whether carboplatin is excreted in human milk. A decision should be made whether to discontinue the drug or to discontinue nursing. When the latter is chosen, replacement of milk by an adequate artificial feeding should be advised to avoid becoming pregnant.

**ADVERSE EXPERIENCES IN PREGNANCY**

- **Drug Interactions**
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  - Carboplatin Injection may cause fetal harm when administered to pregnant women. It is not known whether carboplatin is excreted in human milk. A decision should be made whether to discontinue the drug or to discontinue nursing. When the latter is chosen, replacement of milk by an adequate artificial feeding should be advised to avoid becoming pregnant.

**Dosage and Administration**

- Carboplatin Injection is contraindicated in patients who have been previously treated with cyclophosphamide, have not been established (see CLINICAL STUDIES and ADVERSE REACTIONS).
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In response between elderly and younger patients, but greater sensitivity of some older patients cannot be ruled out. Because renal abnormalities of diuretic drugs are increased in the elderly, renal function should be considered in the selection of carboplatin dosage (see DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS

Myelosuppression is the most common toxicity of carboplatin when administered with cyclophosphamide, see CLINICAL STUDIES. The incidence of severe myelosuppression following combination with cyclophosphamide, see CLINICAL STUDIES.

Treatment of Ovarian Cancer, Comparative Toxicity

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Neutropenia</th>
<th>Anemia</th>
<th>Thrombocytopenia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carboplatin</td>
<td>&lt; 50,000/mm3</td>
<td>&lt; 8 g/dL</td>
<td>&lt; 50,000/mm3</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>&lt; 100,000/mm3</td>
<td>&lt; 10 g/dL</td>
<td>&lt; 100,000/mm3</td>
</tr>
</tbody>
</table>

The nadir usually occurs about 10 to 28 days after completion of treatment, but greater sensitivity of some older patients cannot be ruled out. Because renal abnormalities of diuretic drugs are increased in the elderly, renal function should be considered in the selection of carboplatin dosage (see DOSAGE AND ADMINISTRATION).

The incidence of abnormalities observed during carboplatin treatment may be responsible for the differences that can be noted in the adverse reactions profile seen in patients treated with carboplatin and cyclophosphamide. In a subset of patients, the duration of treatment may be responsible for the differences seen in the adverse reactions profile of patients treated with carboplatin alone versus carboplatin in combination with cyclophosphamide.

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by carboplatin, another drug you may be taking, or your illness. Because some of these effects may be serious, your doctor or other healthcare provider may want to check your blood or give you other medicine to prevent or treat these effects.

The most serious side effects of Carboplatin Injection are:

- Bleeding and reduced blood cells, including reduced red blood cells (anemia) and platelets (needed for proper blood clotting), which may be severe enough to require blood transfusion. You should tell your doctor right away if you notice any unusual bruising or bleeding, especially from cuts, nosebleeds, or black tarry stools or blood in the urine.
- Infections. Carboplatin injection can temporarily lower the number of white blood cells in your blood, increasing the risk of infection.
- Life-threatening allergic reactions – during and after treatment the doctor or nurse will observe you carefully for signs of allergic reaction.
- Kidney and liver problems:
  - Loss of hearing or ringing in the ears
  - Contact your doctor right away if you experience any of these effects, or notice effects that worry you or are troublesome.

Of the less serious side effects associated with Carboplatin Injection, the most common are nausea, vomiting, diarrhea, loss of appetite, hair loss, numbness, tingling, burning, or pain in the hand or feet.

This medicine was prescribed for your particular condition. It must be given under close medical supervision by a doctor trained in the use of drugs for the treatment of cancer.

This summary does not include everything there is to know about Carboplatin Injection. Medicines are sometimes prescribed for purposes other than those listed in patient leaflets. If you have questions about the side effects, benefits, or risks of this medicine, ask your doctor or pharmacist.

Discuss the benefits and risks of Carboplatin Injection with your doctor. Remember, no written information can take the place of your doctor’s experience and advice.

The Patient Information Leaflet has been approved by the U.S. Food and Drug Administration.

Read this entire leaflet carefully. Keep it for future reference.

**CARBOplatin Injection**

We only

This information will help you learn more about Carboplatin Injection. It is neither intended to cover all possible warnings or side effects related to Carboplatin Injection, and it does not list all of the benefits and risks of Carboplatin Injection. Your doctor should always be your first choice for any questions or concerns you may have about your treatment. Be sure to ask your doctor about any questions you may have.

**What is cancer?**

Uncontrolled cell growth is called cancer. Cells grow and divide in an uncontrolled way to form a tumor. Cancer cells can be different from normal cells because they grow without control or regulation. They may interfere with the growth of normal cells as well as cancer cells.

A malignant tumor can spread (metastasize) from its original location to other parts of the body. What is Carboplatin Injection? 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.

Who should not take Carboplatin Injection? Treatment with Carboplatin Injection is not recommended in people who:

- Are allergic to carboplatin or other platinum-containing products
- Have a weakened blood-forming system (bone marrow depression) or significant bleeding

Who should take Carboplatin Injection? Carboplatin Injection 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.

What should I avoid while taking Carboplatin Injection? If you are allergic to carboplatin or other platinum-containing products:

- You are or intend to become pregnant, since carboplatin may harm the developing fetus. It is important to use effective birth control while you are taking Carboplatin Injection.
- You are breastfeeding. Carboplatin may harm your baby.
- You are taking other medicines, including all prescription and non-prescription (over-the-counter) drugs, since carboplatin may affect the action of other medicines.
- You have any medical problems, especially those related to cancer treatment and during chemotherapy. This includes a history of bone marrow depression or other problems with the blood or the immune system. These problems can increase the risk and severity of these conditions.

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- You have any medical problems, especially those related to cancer treatment and during chemotherapy. This includes a history of bone marrow depression or other problems with the blood or the immune system. These problems can increase the risk and severity of these conditions.

What are the possible side effects of Carboplatin Injection? Carboplatin Injection may cause unwanted effects, particularly because Carboplatin interferes with the growth of normal cells as well as cancer cells. For example, the occurrence of another cancer (secondary malignancy) has been reported in patients receiving cancer chemotherapy. However, it may not be possible to tell whether such effects are caused by carboplatin, another drug you may be taking, or your illness. Because some of these effects may be serious, your doctor or other healthcare provider may want to check your blood or give you other medicine to prevent or treat these effects.
by carboplatin, another drug you may be taking, or your immune system. Because some of these effects may be serious, do not stop taking this medicine without first checking with your doctor.

The most serious side effects of Carboplatin Injection are:

- bleeding and reduced blood cells, including reduced red blood cells (anemia) and platelets (needed for proper blood clotting), which may be severe enough to require blood transfusion. You should tell your doctor right away if you notice any unusual bruising or bleeding, including black tarry stools or blood in the urine.

- infection—Carboplatin injection can temporarily lower the number of white blood cells in your blood, increasing the risk of infection.

- life-threatening allergic reaction—during and after treatment the doctor or nurse will observe you carefully for signs of allergic reaction.

- kidney and liver problems:
  - loss of hearing or ringing in the ears: Contact your doctor right away if you experience any of these effects, or notice effects that worry you or are uncomfortable.

Of the less serious side effects associated with Carboplatin Injection treatment, the most common are nausea, vomiting, diarrhea, loss of appetite, hair loss and numbness, tingling, burning, or pain in the hands or feet. This medicine was prescribed for your treatment. Your doctor will determine the dose of Carboplatin Injection for you based on your weight, height, the cancer you have, and other factors. Only a professional experienced in the use of cancer drugs should give you this medication. Treatment with Carboplatin Injection is not recommended if you:

- have a weakened blood-forming system (bone marrow depression) or significant bleeding; or
- have a weakened blood-forming system; or
- are allergic to carboplatin or other platinum-containing products;
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What is Carboplatin Injection?

Carboplatin Injection is a medicine that is used to treat cancer of the ovary. It acts by interfering with the growth of normal cells as well as cancer cells. For example, the occurrence of another cancer (secondary malignancy) has been reported in patients receiving cancer drugs. Carboplatin may cause unwanted effects, particularly because Carboplatin interferes with the growth of normal cells as well as cancer cells. For example, the occurrence of another cancer (secondary malignancy) has been reported in patients receiving cancer drugs. Carboplatin may cause unwanted effects.

What is cancer?

Under normal conditions, the cells in your body divide and grow in an orderly, controlled fashion. Cell division and growth are necessary for the human body to perform its functions and to repair itself. Cancer cells grow and divide in an uncontrolled way. When cancer invades surrounding healthy tissue or spreads to other parts of the body, it is called malignant. A malignant tumor can spread (metastasize) from its original location to other parts of the body. What is Carboplatin Injection? Carboplatin Injection 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.

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Treatment with Carboplatin Injection is not recommended if you:

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- have a weakened blood-forming system; or
- are allergic to carboplatin or other platinum-containing products;
- are allergic to carboplatin or other platinum-containing products.

What should you tell your doctor before starting treatment with Carboplatin Injection?

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

Be sure to inform your doctor:

- if you are allergic to carboplatin or other platinum-containing products;
- if you are or want to become pregnant, since carboplatin may harm the developing fetus; it is important to use effective birth control while you are being treated with Carboplatin Injection.
- if you are breast feeding, since nursing infants may be exposed to carboplatin in this way.
- if you are taking other medicines, including all prescription and non-prescription (over-the-counter) drugs, since carboplatin may affect the action of other medicines.
- if you have any medical problems, especially children (including recent exposure to adults or children with chicken pox), shingles, hearing problems, infection, or kidney disease, since carboplatin may affect the action of other medicines and increase the risk of adverse effects.

What should I avoid while taking Carboplatin Injection?

If you are pregnant or think you might be pregnant, or if you are breast feeding, let your doctor know right away. Carboplatin Injection may harm your developing fetus or breast feeding infants. Carboplatin may cause unwanted effects, particularly because Carboplatin interferes with the growth of normal cells as well as cancer cells. For example, the occurrence of another cancer (secondary malignancy) has been reported in patients receiving cancer drugs. Carboplatin may cause unwanted effects, particularly because Carboplatin interferes with the growth of normal cells as well as cancer cells. For example, the occurrence of another cancer (secondary malignancy) has been reported in patients receiving cancer drugs. Carboplatin may cause unwanted effects.