

Rx only

Patient Information

PARAPLATIN[®]

(generic name = **carboplatin for injection**)

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

This information will help you learn more about PARAPLATIN (carboplatin for injection). It cannot, however, cover all the possible warnings or side effects relating to PARAPLATIN, and it does not list all of the benefits and risks of PARAPLATIN. Your doctor should always be your first choice for detailed information about your medical condition and your treatment. Be sure to ask your doctor about any questions you may have.

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 are different from normal cells because they are not able to control their own growth. The reasons for this abnormal growth are not yet fully understood.

A tumor is a mass of unhealthy cells that are dividing and growing fast and in an uncontrolled way. When a 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.

What is PARAPLATIN?

PARAPLATIN (carboplatin for 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.

Who should not take PARAPLATIN?

Treatment with PARAPLATIN is not recommended if you:

- are allergic to PARAPLATIN or other platinum-containing products, or to mannitol;
- have a weakened blood-forming system (bone marrow depression) or significant bleeding;
- are pregnant, intend to become pregnant, or are breast-feeding a baby.

How is PARAPLATIN used?

Only a professional experienced in the use of cancer drugs should give you this medication. PARAPLATIN is given by dripping the medicine slowly and directly into a vein (intravenous infusion) for 15 minutes or longer. Your doctor will determine the dose of PARAPLATIN for you based on your weight, height, and kidney function. PARAPLATIN may be given alone or with other drugs. Treatment is usually repeated every four weeks for a number of cycles.

Before and after PARAPLATIN treatment, your doctor may give you medication to lessen the nausea and vomiting associated with this cancer treatment.

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

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

Be sure to inform your doctor:

- If you are allergic to PARAPLATIN or other platinum-containing products, or to mannitol;
- If you are or intend to become pregnant, since PARAPLATIN may harm the developing fetus. It is important to use effective birth control while you are being treated with PARAPLATIN;
- If you are breast-feeding, since nursing infants may be exposed to PARAPLATIN in this way;
- If you are taking other medicines, including all prescription and non-prescription (over-the-counter) drugs, since PARAPLATIN may affect the action of other medicines;
- If you have any other medical problems, especially chicken pox (including recent exposure to adults or children with chicken pox), shingles, hearing problems, infection, or kidney disease, since treatment with PARAPLATIN increases the risk and severity of these conditions.

What should I avoid while taking PARAPLATIN?

If you are pregnant or think you might be pregnant, or if you are breast feeding, let your doctor know right away. PARAPLATIN may harm your developing fetus or breast-feeding baby. If you are a woman of childbearing age, you should use birth control to avoid getting pregnant while you are taking PARAPLATIN.

You should avoid contact with adults and children who have infections, and tell your doctor right away if you show signs of infection such as cough, fever, and/or chills. Also, while you are being treated with PARAPLATIN or after you stop treatment, first check with your doctor **before** getting any immunizations (vaccinations). Avoid contact with adults or children who have received oral polio vaccine since they can pass the polio virus to you.

What are the possible side effects of PARAPLATIN?

PARAPLATIN may cause unwanted effects, particularly because PARAPLATIN 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 with multiple drugs. It is not always possible to tell whether such effects are caused by PARAPLATIN, another drug you may be taking, or your illness. Because some of these effects may be serious, you will need close medical supervision during treatment with PARAPLATIN.

The most serious side effects of PARAPLATIN 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** - PARAPLATIN 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 troublesome.**

Of the less serious side effects associated with PARAPLATIN 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 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 PARAPLATIN. Medicines are sometimes prescribed for purposes other than those listed in patient leaflets. If you have questions or concerns, or want more information about PARAPLATIN, your physician and pharmacist have the complete prescribing information upon which this information is based. You may want to read it and discuss it with your doctor. Remember, no written summary can replace careful discussion with your doctor.

Bristol-Myers Squibb Company
Princeton, NJ 08543 USA

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

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this page is the manifestation of the electronic signature.**

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Richard Pazdur
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