

PATIENT MEDICATION INFORMATION
READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Carboplatin Injection BP

Carboplatin injection

Read this carefully before you start taking **Carboplatin Injection BP** and each time you get an infusion. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Carboplatin Injection BP**.

Serious Warnings and Precautions

Carboplatin is a very toxic drug. It is unlikely for this medicine to work without some side effects.

Carboplatin Injection BP can cause serious and possibly fatal side effects including:

- **Serious** and fatal **infections** after receiving some vaccines.
- **Allergic reactions** that may happen within minutes of receiving Carboplatin Injection BP.
- **Myelosuppression**: This is when your blood counts are low. It can affect red blood cells (**anemia**), white blood cells (**neutropenia**) or platelets (**thrombocytopenia**). Myelosuppression can be severe and may increase your risk for infection or bleeding. It may be worse as the number of doses you receive increases. You may need blood transfusions.
- **Vomiting**
- **Fatal hemolytic anemia**: This happens when red blood cells are broken down faster than the body can make new ones.
- **Fatal hemolytic uraemic syndrome**: This happens when there is abnormal breakdown of blood cells which clogs the kidney.
- **Fatal veno-occlusive disease**: This is when the blood vessels leading to and inside the liver are blocked.

What is Carboplatin Injection BP used for?

Carboplatin Injection BP is used to treat adult women with some types of ovarian cancer. It may be given when other treatments have not worked.

How does Carboplatin Injection BP work?

Carboplatin is an anti-cancer medicine, sometimes called chemotherapy. Carboplatin works by preventing the growth of cancer cells and eventually destroying them. Carboplatin can be used alone or in combination with other anti-cancer drugs.

What are the ingredients in Carboplatin Injection BP?

Medicinal ingredients: carboplatin

Non-medicinal ingredients: sterile water for injection

Carboplatin Injection BP comes in the following dosage forms:

Solution: 10 mg / mL

Do not use Carboplatin Injection BP if:

- you are allergic to carboplatin, to any other ingredients in this medicine or to any other medicines that contain platinum;
- you have myelosuppression;
- you have severe kidney disease.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Carboplatin Injection BP. Talk about any health conditions or problems you may have, including if you:

- have recently had or are planning on receiving any vaccinations
- have kidney disease or are taking medications that can damage the kidney. Your doctor will want to monitor you more regularly.
- have been treated with cisplatin or similar anti-cancer medicines in the past. This is because side effects affecting the nervous system are more likely in patients who have received cisplatin previously.
- are over 65 years old.

Other warnings you should know about:

- Carboplatin Injection BP should only be administered to you under the supervision of a qualified physician who is experienced in the use of chemotherapy drugs.
- Carboplatin can cause damage in the ear leading to loss of hearing. You will need to have hearing tests before and during your treatment. These will be repeated if you show signs of hearing loss.
- Tumour lysis syndrome (TLS) is a potentially life-threatening complication. It is caused by chemical disturbances in the blood when cancer cells breakdown and release their contents. If you are higher risk of TLS, your healthcare professional may follow you more closely.
- **Female patients – Pregnancy and breastfeeding:**
 - If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
 - Avoid becoming pregnant while you are using Carboplatin Injection BP. It could harm your unborn baby.
 - Use effective birth control each time you have sex during your treatment and for at least 7 months after your last dose.
 - If you do get pregnant during your treatment, tell your healthcare professional right away.
 - Carboplatin passes into breastmilk. Avoid breastfeeding during your treatment and 1 month after the end of your treatment.

- **Male patients – Pregnancy:** Use effective birth control each time you have sex with a woman who could get pregnant. You should use this birth control during your treatment and for at least 4 months after your last dose.
- **Fertility – male and female patients:** Treatment with Carboplatin Injection BP may affect your ability to have a child in the future. Talk to your healthcare professional if you have questions about this.
- **Tests:** During your treatment with Carboplatin Injection BP, you will have regular blood and urine tests. The results of these tests will tell your healthcare professional how the treatment is affecting your blood, liver and kidneys. Your healthcare professional will also check you for blood clots, nerve damage and hearing loss.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Carboplatin Injection BP:

- Medicines used to treat bacterial infections called aminoglycosides
- Medicines which can reduce the number of cells in your blood
- Medicines that can affect or damage your kidneys
- Medicines used to treat convulsions and seizures called phenytoin and fosphenytoin

How to take Carboplatin Injection BP:

Carboplatin Injection BP will be given to you by a healthcare professional. It will be given by infusion (drip) over 15 to 60 minutes. This means Carboplatin Injection BP will be given through a tube placed into one of your veins.

Usual dose:

Your healthcare professional will work out the correct dose of Carboplatin Injection BP for you. It will depend on your medical condition, your height and weight and how well your kidneys are working. Your healthcare professional will also tell you how often you will receive Carboplatin Injection BP. There will be about 4 weeks between each dose.

Your healthcare professional may change your dose of Carboplatin Injection BP or stop your treatment completely. This can happen if you experience certain side effects.

Overdose:

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns. Too much Carboplatin Injection BP may affect your blood count, kidneys, or liver. Tell your healthcare professional if you have extreme fatigue, diarrhea, hair loss or abnormal vision.

If you think you, or a person you are caring for, have taken too much Carboplatin Injection BP, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose, your healthcare professional will decide when you should receive the next one.

What are possible side effects from using Carboplatin Injection BP?

These are not all the possible side effects you may have when taking Carboplatin Injection BP. If you experience any side effects not listed here, tell your healthcare professional.

- nausea
- flu-like symptoms
- tingling or numbness in your hands, feet, arms or legs
- burning or prickling sensation
- decreased tendon reflex
- taste disturbance or loss of taste
- ringing in the ears or changes in your hearing
- diarrhea or constipation
- sore lips or mouth ulcers
- hair loss
- rash and/or itchy skin
- pain or discomfort in your bones, joints, muscles, or surrounding structures
- skin disorders such as hives, rash, skin redness, and itching
- swelling or soreness where the injection was given

Carboplatin Injection BP can cause abnormal blood test results. Your healthcare professional will do regular blood tests and will interpret the results. The results of these tests will tell your healthcare professional how Carboplatin Injection BP is affecting your blood, kidneys and liver. The results may also tell them if you have gout.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Unknown frequency			
Severe allergic reaction (anaphylaxis / anaphylactic reactions): sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat, difficulty swallowing or breathing, tightness of the chest or wheezing, feeling faint, death			X

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
<p>Myelosuppression including:</p> <p>Anemia (low red blood cells): fatigue, loss of energy, pale skin, shortness of breath, weakness</p> <p>neutropenia (low white blood cells): signs of infection such as a sore throat and high temperature</p> <p>thrombocytopenia (low platelets): abnormal bruising, bleeding</p>		X	
<p>Hemolytic-uraemic syndrome (when blood vessels in the kidney are damaged or inflamed): decreased or no urine, blood in the urine, diarrhea, abdominal pain, vomiting and fever, death</p>			X
<p>Tumour lysis syndrome (the sudden, rapid death of cancer cells due to the treatment): muscle cramping, muscle weakness, confusion, visual loss or disturbances, irregular heartbeat, kidney failure or abnormal blood test results</p>		X	
<p>Hepatic veno-occlusive disease (blocked blood vessels leading to and inside the liver): enlarged liver, swelling and pain in the upper right abdomen, weight gain, yellowing of the skin and whites of eyes (jaundice), death</p>		X	
<p>Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), or erythema multiforme (EM) (severe skin rashes that may become life threatening): reddish target-like spots or circular patches, blisters or peeling of the skin, blisters in the mouth, red and swollen eyes. The skin changes happen quickly and may follow fever, tiredness, headache, and cough</p>			X
<p>Hemolytic anemia (decrease number of red blood cells): fatigue, loss of energy, pale skin, shortness of breath, weakness</p>		X	
<p>Serious and fatal infections: sore throat and high temperature</p>		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Vision problems: temporary worsening of eyesight or changes to your vision, temporary loss of sight		X	
Liver problems: yellowing of the skin and eyeballs, pain in your abdomen, abdominal swelling, nausea, vomiting, feeling unwell, confusion, sleepiness		X	
Kidney problems: decreased urine output, swelling of legs, ankles or feet, shortness of breath, fatigue, confusion, nausea, weakness, irregular heartbeat		X	
Secondary blood malignancies (new cancers that affect the blood); fatigue, shortness of breath, paleness, bruising or bleeding, red spots under the skin, frequent infections, fever, bone pain, loss of appetite, nausea, night sweats, swollen lymph nodes, weight loss		X	
Posterior Reversible Encephalopathy Syndrome (PRES; swelling of some parts of the brain): headache, confusion, seizures, and visual disturbances (blurred vision, loss of sight), changes in mental function		X	
Stroke (lack of blood flow to the brain): sudden loss of speech or numbness of part or all of the body, loss of vision or blurred vision, unexplained dizziness and/or sudden falls		X	
Heart Failure (heart does not pump blood as well as it should): feeling dizzy, fatigue and weakness, lightheaded, shortness of breath, feeling like your heart is pounding, racing, beating irregularly, fluid retention, lack of appetite, nausea, swelling in the ankles, legs and feet		X	
Embolism (when the flow of blood is blocked within a blood vessel): chest pain, shortness of breath, dizziness, fainting, nausea, irregular heartbeat, palpitations, coughing, sweating		X	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Get immediate medical help
	Only if severe	In all cases	
Encephalopathy (mental changes): symptoms may include changes in memory, difficulty focusing, change in personality, fatigue, progressive loss of consciousness		X	
Pain in abdomen (sometimes fatal)	X		
Asthenia: extreme tiredness or weakness (sometimes fatal)	X		
Vomiting	X		
Kounis syndrome: acute coronary syndrome (chest pain with radiation to the next or left arm, pale skin, sweating, shortness of breath) caused by a severe allergic reaction (see Severe allergic reaction side effect above in this table, for symptoms).		X	

If you experience any side effects not listed here, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Your healthcare professional will store Carboplatin Injection BP vials between 15 and 25°C, protected from light and freezing.

If you want more information about Carboplatin Injection BP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this

Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pfizer.com/ca, or by calling 1-800-463-6001.

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