

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### Cisplatin Injection BP

#### Cisplatin injection sterile solution

Read this carefully before you start taking **Cisplatin Injection BP** and each time you get an injection. 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 **Cisplatin Injection BP**.

#### Serious Warnings and Precautions

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

- **Severe allergic reactions** that may happen within minutes of receiving Cisplatin Injection BP.
- **Serious and fatal Infections**, including sepsis (severe reaction to an infection), which can result from a reduced white blood cell count (cells responsible for fighting against an infection).
- **Serious and fatal bone marrow suppression** which may result in reduced white blood cells and platelets.
- **Neurotoxicity** (damage to the nervous system, including the brain and peripheral nervous system):
  - **Leukoencephalopathy** (change in the matter of the brain). Some cases have been fatal.
  - **Peripheral neuropathy** (damage to the nerves outside of your brain or spinal cord) .
  - **Posterior reversible encephalopathy** syndrome (swelling of some parts of the brain).
- **Kidney problems**, including reduced urine output, swelling of legs, ankles or feet.
- **Cardiovascular problems**, such as blood clots in the veins or lungs which can lead to a heart attack or stroke. Some cases have been fatal.

Receiving cisplatin before receiving paclitaxel may increase paclitaxel levels in the blood and increase neutropenia (decreased white blood cells) and neurotoxicity (damage to the nervous system).

#### What is Cisplatin Injection BP used for?

Cisplatin Injection BP is used to treat some types of:

- ovarian cancers
- cancer to the testes
- cancer to the bladder

#### How does Cisplatin Injection BP work?

Cisplatin Injection BP belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear it referred to as a chemotherapy medicine. Cisplatin Injection BP may be used alone or with other anticancer therapies.

Cisplatin Injection BP contains platinum and is used as an anticancer drug to interfere with the growth of cancer cells and eventually destroy them.

Cancer cells are like normal cells which have changed so that they grow out of control in the body. Since the growth of normal body cells may also be affected by cisplatin, other effects may also occur (see **What are possible side effects from using Cisplatin Injection BP**).

### **What are the ingredients in Cisplatin Injection BP?**

Medicinal ingredients: Cisplatin

Non-medicinal ingredients: hydrochloric acid, mannitol, sodium chloride, sodium hydroxide, and water for injection.

### **Cisplatin Injection BP comes in the following dosage forms:**

Cisplatin Injection BP, 1 mg / mL.

Supplied as a sterile aqueous solution for intravenous use. Available in amber glass ONCO-TAIN® vials of 50 mL and 100 mL. Each single-use vial is individually packaged in a carton.

Cisplatin Injection BP is preservative-free.

### **Do not use Cisplatin Injection BP if:**

- you are allergic to cisplatin or to any of the other ingredients of this medicine (listed in **What are the ingredients in Cisplatin Injection BP**)
- you have had allergic reactions to similar anti-cancer medicines (like those containing platinum) in the past
- you have kidney problems (unless otherwise told by your healthcare professional)
- you have hearing problems (unless otherwise told by your healthcare professionals)
- you have very low numbers of blood cells (a condition called ‘myelosuppression’). Your healthcare professional will check this with a blood test.

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

- Have recently received or plan to receive vaccines.
- Are taking medications that can damage the kidney. Your healthcare professional will check on you more regularly.
- Heart problems
- A problem with blood clots forming in your blood vessels, such as:
  - painful inflammation of the veins (thrombophlebitis);
  - blockage of blood vessels in the legs (deep vein thrombosis or DVT);
  - lungs (pulmonary embolism).
- Anaemia or bone marrow depression (such as low red blood cells, low white blood cells or low platelets).
- Any sort of infections (such as sinusitis or tooth abscess).

- Hearing problems.
- Kidney problems.
- Liver disease.
- Numbness or weakness of the arms and legs.
- Dizziness or being light-headed, especially on standing up.
- Problems with your vision.
- Muscle problems.
- Low magnesium or calcium levels.

**Other warnings you should know about:**

- **Children (under 18 years old):**
  - Hearing problems resulting from use of Cisplatin Injection BP may be more severe in children, especially those less than 5 years old.
- **Adults (Ages 65 and older):**
  - Adults ages 65 and older may be more likely to experience side effects like reduced bone marrow function, kidney problems, and nerve problems.
- Do not have any vaccinations without talking to your healthcare professional first while you are being treated with Cisplatin Injection BP.
- **Female patients – Pregnancy and breastfeeding**
  - Avoid becoming pregnant while you are using Cisplatin Injection BP. It could harm your unborn baby.
  - If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
  - 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.
  - Cisplatin passes into breastmilk. Avoid breastfeeding during your treatment and for 1 month after your last dose.
- **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 – female and male patients**
  - Treatment with Cisplatin 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 Cisplatin 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 Cisplatin Injection BP:**

- Medicines used for the treatment of seizures (e.g., phenytoin, carbamazepine, valproate sodium).
- Medicines that are toxic to the kidneys such as some antibiotics (aminoglycosides) and some anti-cancer drugs, such as ifosfamide.
- Medicines that are removed or eliminated by the kidneys, such as lithium (used for bipolar disorder).
  - Cisplatin Injection BP may reduce the amount of lithium in the blood when Cisplatin Injection BP is used together with bleomycin and etoposide (other anti-cancer drugs).
  - Lithium blood levels should be monitored during treatment.
- Medicines that can cause hearing problems (hearing loss or balance problems) such as aminoglycoside antibiotics or loop diuretics.
- Medicines that thin the blood (such as coumarin, warfarin).
- Paclitaxel (used to treat cancer).

### **How to take Cisplatin Injection BP:**

Cisplatin Injection BP should only be given to you by a healthcare professional who specializes in chemotherapy drugs.

Cisplatin Injection BP is given by a slow injection into a vein.

### **Usual dose:**

Your healthcare professional will decide what dose of Cisplatin Injection BP is right for you. They will also decide how often and how long you will receive it. This depends on your condition and other factors, such as:

- your weight,
- your age,
- blood tests,
- how well your kidneys, liver and ears are working,
- whether or not other medicines are being given at the same time.

There will be about 3 to 4 weeks between each dose.

Additional fluid is given before and after your dose of Cisplatin Injection BP. Since Cisplatin can affect your kidneys, additional fluid can help to keep your kidneys from getting damaged.

Your healthcare professional may change your dose of Cisplatin 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 healthcare professional. It is unlikely that you will be given too much or too little, however, tell your healthcare professional if you have any concerns. In case of overdose, you may experience increased side effects. Your healthcare professional may give you other treatments to address the symptoms of these side effects.

If you think you, or a person you are caring for, have taken too much Cisplatin 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 Cisplatin Injection BP?**

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

- Fast heart rate (tachycardia)
- Low blood pressure (hypotension)
- Inflammation of the blood vessels of the head (cerebral arteritis)
- Vomiting
- Eating disorder characterized by abnormally low body weight (anorexia)
- Diarrhea
- Inflammation of the mouth (stomatitis)
- Joint pain (arthralgia)
- Muscle pain (myalgia)
- Tuberculosis
- Hair loss (alopecia)
- Abnormal sperm production (abnormal spermatogenesis)
- No sperm count (azoospermia)
- Low magnesium count in blood (hypomagnesemia)
- Low calcium count in blood (hypocalcemia)
- Low sodium count in blood (hyponatremia)
- Low potassium count in blood (hypokalemia)
- Low phosphorus count in blood (hypophosphatemia)
- Fever (pyrexia)
- Lack of energy and strength (asthenia)
- Nose bleeds
- Loss of appetite
- Constipation
- Colour blindness
- Swelling of the optic nerve that connects the eye and brain (papilledema)
- Fatigue
- Dehydration
- High blood pressure (hypertension)
- Enlarged breasts (gynecomastia)

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><b>Severe allergic reaction</b> (anaphylaxis / anaphylactic reaction): you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), flushing and you may feel you are going to faint</p>			X
<p><b>Myelosuppression</b> (decrease in bone marrow function which can affect the production of blood cells)</p> <ul style="list-style-type: none"> <li>• <b>Leukopenia</b> (low white blood cells): signs of infection such as a sore throat and high temperature</li> <li>• <b>Thrombocytopenia</b> (low platelets): abnormal bruising, bleeding</li> <li>• <b>Anemia</b> (low red blood cells): fatigue, loss of energy, pale skin, shortness of breath, weakness</li> </ul>		X	
<p><b>Infection / Sepsis</b> (severe reaction to an infection): fever and chills, difficulty breathing, sweating, fast heart rate and mental confusion.</p>			X
<p><b>Pulmonary embolism</b> (blood clot in the lung): chest pain, difficulty breathing, shortness of breath, dizziness, cough, irregular heartbeat.</p>			X
<p><b>Deep vein thrombosis</b> (blood clot in leg): severe leg pain, swelling in leg, warm skin of red or darkened color around painful area.</p>			X
<p><b>Heart attack</b> (lack of blood flow to the heart): severe chest pain possible radiating to the jaw or arm, sweating, shortness of breath, nausea</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	
<b>Stroke</b> (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
<b>Kidney failure:</b> reduced urination, joint pain, swelling of feet or lower legs, pain in the lower back or side		X	
<b>Hemolytic anemia</b> (decreased number of red blood cells): fatigue, loss of energy, pale skin, shortness of breath, weakness		X	
<b>Posterior Reversible Encephalopathy Syndrome (PRES)</b> (swelling of some parts of the brain): headache, confusion, seizures, and visual disturbances (blurred vision, loss of sight), changes in mental function		X	
<b>Leukoencephalopathy</b> (disease of the white matter of the brain): Clumsiness or loss of coordination, difficulty walking, facial drooping, trouble speaking weak muscles, personality changes		X	
<b>Peripheral neuropathy of the sensory nerves:</b> tickling, itching or tingling without cause and sometimes with loss of taste, touch, sight, sudden shooting pains from the neck through the back and into the legs when bending forward		X	
<b>Ototoxicity (damage to the ear): loss of hearing,</b> ringing in the ears, balance problems.		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	
<b>Secondary acute leukemia</b> (type of blood cancer that you can get after chemotherapy or radiation): fever of chills, frequent or severe infections, weight loss, swollen lymph nodes, easy bleeding or bruising.		X	
<b>Nausea and vomiting</b>	X		
<b>Ocular toxicity</b> (vision problems): loss of vision, blurred vision, altered color perception, eye pain.		X	
<b>Extravasation (medication leaking out of the vein into surrounding tissue):</b> painful stinging or burning sensation, swelling, and skin discoloration, around the injection site.			X
<b>Renal toxicity / nephrotoxicity</b> (problems with your kidneys): swelling in your hands, ankles, feet or other areas of your body, nausea and vomiting, shortness of breath, muscle cramps, loss of appetite, urinating either too much or too little, blood in urine.		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, 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.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 Cisplatin Injection BP vials at room temperature, between 15°C and 25°C. Protect from light and freezing.

Cisplatin is cytotoxic. This means that it can damage cells. It should be handled by your healthcare professional with protective equipment.

### If you want more information about Cisplatin 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 <https://www.pfizer.ca>, or by calling 1-800-463-6001.

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