

# DBL™ Cisplatin Injection

*Cisplatin (siss-PLAT-in)*

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about DBL™ Cisplatin Injection.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given cisplatin against the benefits they expect it will have for you.

**If you have any concerns about this medicine, ask your doctor or pharmacist.**

Keep this leaflet in a safe place.

You may need to read it again.

### What DBL™ Cisplatin Injection is used for

DBL™ Cisplatin Injection belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear it referred to as a chemotherapy medicine.

This medicine is used to treat:

- ovarian cancer
- bladder cancer
- cancer of the head and neck

DBL™ Cisplatin Injection is a platinum-containing medicine 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 **Side Effects**).

DBL™ Cisplatin Injection may be used alone or with other anticancer therapies.

DBL™ Cisplatin Injection has been chosen as your therapy, as the benefits of treatment are expected to be greater than the unwanted or side effects.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

### Before you are given DBL™ Cisplatin Injection

*When you must not be given it*

**You should not be given DBL™ Cisplatin Injection if you have an allergy to cisplatin, other platinum-containing compounds or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction to cisplatin may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**DBL™ Cisplatin Injection should not be given if:**

- you have kidney disorders

- you have impaired hearing
- you have bone-marrow disease.

**You should not be given DBL™ Cisplatin Injection if you are pregnant.**

DBL™ Cisplatin Injection may affect your developing baby if you are given it during pregnancy.

It is recommended that you and your doctor discuss your need for cisplatin treatment during pregnancy and the possible risks and benefits of using cisplatin during pregnancy.

Cisplatin may cause birth defects if you or your partner are being treated with it at the time of conception or, if cisplatin is given to females already pregnant. It is best to use some kind of birth control during your treatment with cisplatin. You must tell your doctor immediately if you suspect you are pregnant.

Cisplatin may have a prolonged effect on fertility in males and females. Your doctor should discuss this issue with you before you begin therapy with cisplatin.

**DBL™ Cisplatin Injection should not be given to you if you are breastfeeding or plan to breastfeed.**

As the possible harmful effects to the infant are not known, breastfeeding is not recommended while you are receiving cisplatin.

**If you are not sure whether you should be given cisplatin, talk to your doctor or pharmacist.**

*Before you are given it*

**Tell your doctor or pharmacist if you have allergies to:**

- any other medicines

- any other substances, such as foods, preservatives or dyes.

Before you receive cisplatin your doctor will take a full history of your medical conditions and tests such as blood cell counts, hearing tests, kidney function tests and liver function tests may be carried out before, during and after treatment.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- hearing problems
- kidney problems
- anaemia or bone marrow depression
- liver disease
- low magnesium or calcium levels
- herpes zoster infections (also known as shingles)
- chicken pox (now or recently), or if you have been in recent contact with someone who has chicken pox
- a problem with blood clots forming in your blood vessels, such as painful inflammation of the veins (thrombophlebitis) or blockage of blood vessels in the legs (deep vein thrombosis or DVT), or lungs (pulmonary embolism).

**If you have not told your doctor or pharmacist about any of the above, tell them before you are given DBL™ Cisplatin Injection.**

### *Taking other medicines*

**Tell your doctor or pharmacist if you are taking/using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and cisplatin may interfere with each other. These include:

- aminoglycoside antibiotics, such as gentamicin, amikacin or tobramycin
- loop diuretics, such as frusemide or ethacrynic acid

- anti-gout medicines such as probenecid and sulphinpyrazone
- aspirin
- alcohol.

These medicines may be affected by cisplatin, or may affect how well it works. You may need different amounts of your medicine, or different medicines. Your doctor or pharmacist will advise you.

While you are being treated with cisplatin, and for about one month after you stop treatment with it, **do not have any immunisations (vaccinations) without your doctor's approval.**

Cisplatin may lower your body's resistance and there is a chance you may get the infection the immunisation is meant to prevent. In addition, other persons living in your household should not take oral polio vaccine (sabin) since there is a chance they could pass the polio virus on to you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given DBL™ Cisplatin Injection.

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## How DBL™ Cisplatin Injection is given

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### *How much is given*

The dose of cisplatin will be different for different patients.

Your doctor will decide what dose you will receive. This depends on the cancer being treated, your weight, physical condition and other factors, such as the results of your kidney and blood tests.

### *How it is given*

DBL™ Cisplatin Injection should only be given by a doctor or nurse.

DBL™ Cisplatin Injection is given as a continuous slow infusion into a vein. A cycle of treatment may be given as a single dose in a day or as

a number of doses over several days.

### *How long it is given for*

Several cycles of cisplatin therapy may be needed, depending on your response to treatment.

**Treatment cycles** may be repeated every three or four weeks.

You will be treated in the clinic under close supervision of medical and nursing staff.

**Adequate fluid intake** is important so you may be given fluids intravenously before, during and after treatment.

### *Overdose*

**As DBL™ Cisplatin Injection is administered under the care of a highly trained doctor, it is unlikely that you will receive an overdose. However, if you experience severe side effects tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital.**

**In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand)**

Symptoms of a cisplatin overdose include the side effects listed below in the "Side Effects" section, but are usually of a more severe nature.

**Ask your doctor, nurse or pharmacist if you have any concerns.**

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## While you are being given DBL™ Cisplatin Injection

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### *Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Cisplatin.**

**Tell any other doctors, dentists, and pharmacists who treat you**

**that you are being given this medicine.**

Cisplatin therapy may delay healing and increase bleeding from the gums, so avoid any dental work if possible.

**If you are going to have surgery, tell the surgeon or anaesthetist you are being given this medicine.**

**If you become pregnant while you are being treated with this medicine, tell your doctor immediately.**

**Keep all of your doctor's appointments so that your progress can be checked.**

It is important to have your follow-up cycles of cisplatin at the appropriate times to get the best effects from your treatments.

While you are being treated with cisplatin your doctor will monitor your condition and take blood for tests prior to each treatment cycle.

Blood tests are carried out as cisplatin affects the body's ability to produce blood cells. Three types of blood cells are checked before each treatment:

- platelets, involved with the control of bleeding,
- white blood cells, involved with fighting infection and
- red blood cells, involved in moving oxygen around the body.

Low red cell counts may indicate that you may require a blood transfusion or your next dose of cisplatin may be delayed or varied.

**Take the following precautions to reduce your risk of infection or bleeding:**

- avoid people with infections. Check with your doctor immediately if you think you are getting an infection, or if you get a fever or chills, cough or hoarseness, lower back or side pain, or find it painful or difficult to urinate;
- check with your doctor immediately if you notice any unusual bleeding or bruising,

black stools, blood in urine or stools or pinpoint red spots on your skin;

- be careful when using a regular toothbrush, dental floss or toothpick. Your doctor or nurse may recommend other ways to clean your teeth and gums. Check with your doctor before having any dental work done;
- be careful not to cut yourself when you are using sharp objects such as a safety razor or nail cutters;
- avoid contact sports or other situations where you may get bruised or injured.

Blood and urine tests are taken to check how well your kidneys are functioning. Your dosage of cisplatin may be delayed or varied depending on your kidney function.

**As cisplatin often causes nausea and vomiting, your doctor will give you medication to prevent you feeling sick.**

Your symptoms will be better managed if you take your medication regularly to prevent sickness rather than use it only when sickness occurs.

**Tell your doctor or pharmacist if you have any concerns about this.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how cisplatin affects you.**

If you feel weak, dizzy or nauseated, avoid driving, smoking, operating machinery or taking other medicines unless your doctor tells you to.

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, dizziness or light-headedness may be worse.

Alcohol and aspirin should be avoided because of the risk of gastrointestinal bleeding.

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## Side effects

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**Check with your doctor, pharmacist or nurse as soon as possible if you have any problems while you are being given cisplatin, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.**

Like other medicines, cisplatin may cause some side effects. Some of these side effects may be prevented or treated by therapy with other medicines. If side effects do occur, their severity usually depends on the dose of cisplatin you receive.

The effects of cisplatin may take some time to occur and therefore the side effects may be delayed. It is possible that the unwanted side effects may not occur until months after Cisplatin Injection is given.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- nausea and vomiting
- loss of appetite
- temporary hair loss
- tingling or loss of sensation in the fingers and toes
- feeling tired or weak
- fever, chills
- mouth ulcers
- skin rashes, particularly at the site of infusion.

These are the more common side effects of DBL™ Cisplatin Injection.

**If any of the following happen, tell your doctor, pharmacist or nurse immediately, or go to the Emergency department at your nearest hospital:**

- signs of an allergic reaction (such as shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin; dizziness or light-headedness)

- changes in the rhythm or rate of the heart beat
- signs of infection, such as fever, chills, sore throat or mouth ulcers
- uncontrollable nausea and vomiting,
- extreme weakness
- kidney failure ( reduced urination, joint pain, swelling of feet or lower legs, pain in the lower back or side )
- deafness or hearing problems
- tinnitus (ringing in the ears)
- unusual bleeding or bruising.
- reduced urination, swelling of feet or lower legs
- cramps, muscle irritability, tremors, seizures or spasms
- pain in the joints, lower back or side
- unusual bleeding such as bleeding gums, blood in urine or stools, unusual bruising or pinpoint red spots on the skin
- blurred vision, altered colour perception.

These may be serious side effects. You may need urgent medical treatment or hospitalisation.

**Other side effects not listed may also occur in some patients.**

Tell your doctor if you notice anything else that is making feel unwell.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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## After being given DBL™ Cisplatin Injection

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Continue drinking plenty of fluids.

Your doctor will continue to monitor your medical condition before your next cycle of treatment.

Tell your doctor immediately if you have unwanted side effects which continue after your treatment has stopped.

## Storage

DBL™ Cisplatin Injection should be stored in the pharmacy or ward at room temperature (between 15-25°C) away from light and out of reach of children.

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## Product description

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### *What it looks like*

DBL™ Cisplatin Injection is a sterile, aqueous, preservative-free clear colourless to pale yellow solution in glass vials.

### *Ingredients*

Active ingredient:

- Cisplatin

Other ingredients:

- mannitol
- sodium chloride
- water for injections

DBL™ Cisplatin Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### *Sponsor*

#### **Australian Sponsor:**

Hospira Australia Pty Ltd  
ABN 58 097 064 330  
Level 3  
500 Collins Street,  
Melbourne VIC 3000  
Australia

Toll Free Number: 1800 675 229

#### **New Zealand Sponsor:**

Pfizer New Zealand Limited,  
PO Box 3998  
Auckland, New Zealand, 1140  
Toll Free Number: 0800 736 363

DBL™ Cisplatin Injection is available in the following strengths and pack sizes:

- 50 mg/50 mL, 1 x 50 mL vial.  
AUST R 47275
- 100 mg/100mL, 1 x 100mL vial.  
AUST R 47276.

This leaflet was updated in September 2017.