

DBL™ Cisplatin Injection

cisplatin

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 taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

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:

- testicular cancer
- 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

Do not use DBL Cisplatin Injection if you have an allergy to:

- any medicine containing cisplatin
- any other platinum-containing compounds
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction 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 a low blood count.

Do not use this medicine if you are pregnant.

It 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.

Females: Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Avoid becoming pregnant by using effective birth control during your treatment with cisplatin and for at least 26 weeks after you stop treatment (at least 31 weeks if have kidney disease). You must tell your doctor immediately if you suspect you are pregnant.

Males: Tell your doctor or pharmacist if your partner intends to become pregnant while you are being given cisplatin, or shortly after you have stopped treatment.

It is recommended that you use effective contraception while you are

using cisplatin and for at least 14 weeks after you stop treatment (at least 19 weeks if you have kidney disease).

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.

Do not breast-feed if you are using this medicine.

The active ingredient in DBL Cisplatin Injection passes into breast milk and there is a possibility that your baby may be affected. 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 start taking this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant.

Tell your doctor if are breast-feeding or plan to breastfeed.

Tell your doctor if you have or have had any of the following medical conditions:

- hearing problems
- kidney problems
- heart problems
- anaemia or bone marrow depression
- liver disease
- low magnesium or calcium levels
- any sort of infection, particularly 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).

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

If you have not told your doctor about any of the above, tell him/her before you are given DBL Cisplatin Injection.

Taking other medicines

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

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

- antibiotics, such as aminoglycoside antibiotics used to treat infections
- amphotericin B, used to treat fungal infections
- water tablets, such as frusemide, used to treat fluid build up
- lithium, used to treat bipolar disorder or schizophrenia
- anticonvulsants, used to treat seizures
- aspirin or anticoagulants, used to prevent blood clots
- paclitaxel or ifosfamide, used to treat cancer
- antigout medicines, used to prevent or treat gout.

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

Do not have any immunisations (vaccinations) without your doctor's approval while you are being treated with cisplatin.

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 have any immunisations until they check with a doctor since there is a chance they could pass the infection the immunisation is meant to prevent to you.

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

How DBL Cisplatin Injection is given

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.

If you are given too much (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.

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.

Your doctor has information on how to recognise and treat an overdose.

While you are being given DBL Cisplatin Injection

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 that you are taking this medicine.

If you become pregnant while taking 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.

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.

Avoid drinking alcohol while you are being given 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.

Side effects

Check with your doctor, pharmacist or nurse as soon as possible if you have any problems or do not feel well 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. Most are likely to be minor or temporary. However, some may be serious and need medical attention.

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 DBL Cisplatin Injection is given.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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, vomiting, diarrhoea, constipation
- loss of appetite, weight loss
- pain or redness at site of injection
- hair loss, especially of the scalp
- headaches, dizziness, feeling tired or weak
- mouth ulcers.

Tell your doctor as soon as possible if you notice any of the following:

- hearing problems or ringing in the ears (tinnitus)
- eye pain
- bursts of pain that run down the back into the arms and legs
- muscle spasms, weakness, aches or pains
- abnormal paleness, or lack of colour of the skin.

The above list includes serious side effects that may require medical attention.

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

- signs of an allergic reaction (such as shortness of breath, wheezing or difficulty breathing; flushing; 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, tightness or pain of the chest, neck, back or arms
- signs of infection, such as fever, chills, sore throat, sweats or feeling generally unwell
- severe nausea and vomiting
- extreme weakness
- signs of kidney failure (reduced urination, joint pain, swelling of

feet or lower legs, pain in the lower back or side)

- seizures, slurred speech and loss of memory, confusion
- problems with movement or reduced reflexes, and leg weakness
- shaking or tremors, foot spasms
- muscle cramps or twitching
- paralysis or numbness of the face, arm or leg, tingling or a loss of sensation in the hands or feet
- 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 or blindness
- decreased or loss of consciousness
- yellowing of the skin, eyes or mouth, dark urine.

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

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

Other side effects not listed above may also occur in some people.

After being given DBL Cisplatin Injection

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°C to 25°C) away from light and out of reach of children.

Product description

What it looks like

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

Ingredients

DBL Cisplatin Injection contains cisplatin as the active ingredient. Other ingredients include:

- mannitol
- sodium chloride
- water for injections

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

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.

TM = Trademark

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