DBL™ Cisplatin Injection

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being treated with DBL Cisplatin Injection?

DBL Cisplatin Injection contains the active ingredient cisplatin. DBL Cisplatin Injection is used to treat testicular cancer, ovarian cancer, bladder cancer and cancers of the head and neck.

For more information, see Section <u>1. Why am I being</u> <u>treated with DBL Cisplatin Injection?</u> in the full CMI.

2. What should I know before treatment with DBL Cisplatin Injection?

DBL Cisplatin Injection should not be used if you have ever had an allergic reaction to cisplatin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have kidney disease, hearing difficulties, an infection, low blood cell production or any other medical conditions, take any

other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know before treatment with DBL Cisplatin Injection?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Cisplatin Injection and affect how it works. Examples include some medicines to treat bacterial or fungal infections, cancer, and gout; medicine to prevent fits or to reduce the amount of water in the body; and blood thinners, including aspirin.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is DBL Cisplatin Injection given?

Your doctor will give you DBL Cisplatin Injection as a slow injection (drip) into a vein and decide how much you will be given and for how long.

More instructions can be found in Section <u>4. How is DBL</u> <u>Cisplatin Injection given?</u> in the full CMI.

5. What should I know during treatment with DBL Cisplatin Injection?

Things you should do	 Inform your doctor immediately if you are pregnant or experience certain side effects. Remind any doctor, nurse, dentist, surgeon, anaesthetist or pharmacist you visit that you are being treated with DBL Cisplatin Injection.
Driving or using machines	Be careful until you know how DBL Cisplatin Injection affects you.
Drinking alcohol	 Alcohol should be avoided because of the increased risk of bleeding in the mouth, throat, stomach and gut.
Looking after your medicine	 The hospital will store and dispose of the medicine.

For more information, see Section <u>5. What should I know</u> <u>during treatment with DBL Cisplatin Injection?</u> in the full CMI.

6. Are there any side effects?

Side effects include sudden life-threatening allergic reactions (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); infection (fever, fatigue, chills, a sore throat, aches and pains, or coughing); severe nausea and vomiting; reduced urination, joint pain, swelling of feet or lower legs, pain in the lower back or side; headache, seizures, slurred speech and loss of memory, confusion; eye pain, blurring or other changes in your vision; problems with movement or reduced reflexes, and leg weakness; 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/wee or bowel motions/poo, unusual bruising or pinpoint red spots on the skin; changes in the rhythm or rate of the heartbeat, tightness or pain of the chest, neck, back or arms; shortness of breath, chest pain or coughing, yellowing of the skin, eyes or mouth, dark urine.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> effects? in the full CMI.

DBL™ Cisplatin Injection

Active ingredient(s): cisplatin

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Cisplatin Injection. You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using DBL Cisplatin Injection.

Where to find information in this leaflet:

- 1. Why am I being treated with DBL Cisplatin Injection?
- 2. What should I know before treatment with DBL Cisplatin Injection?
- 3. What if I am taking other medicines?
- 4. How is DBL Cisplatin Injection given?
- 5. What should I know during treatment with DBL Cisplatin Injection?
- 6. Are there any side effects?
- 7. Product details

1. Why am I being treated with DBL Cisplatin Injection?

DBL Cisplatin Injection contains the active ingredient cisplatin. DBL Cisplatin Injection is a type of medicine called an anti-neoplastic or cytotoxic agent. You may also hear it referred to as chemotherapy.

Cisplatin blocks DNA production in cancer cells which helps to weaken and destroy them. It may be used alone or in combination with other anti-cancer therapies.

DBL Cisplatin Injection is used to treat testicular cancer, ovarian cancer, bladder cancer and cancers of the head and neck.

2. What should I know before treatment with DBL Cisplatin Injection?

Warnings

DBL Cisplatin Injection should not be used if you have:

- an allergy to cisplatin, other platinum containing compounds, or any of the ingredients listed at the end of this leaflet
- kidney problems
- hearing problems
- reduced amounts of red or white blood cells or platelets
- any infection
- if you are pregnant or breast feeding.

Check with your doctor if you:

- have or have had low iron levels
- have heart problems

- will require dental work or an invasive medical procedure
- have low magnesium or calcium levels
- are going to be given a vaccine
- have been exposed to an infection recently, especially chicken pox or shingles
- have muscle numbness or weakness, or seizures
- have liver problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you or are pregnant or you or your partner intend to become pregnant.

DBL Cisplatin Injection is potentially harmful to the fetus.

Women should use effective contraception during treatment with DBL Cisplatin Injection and for at least 7 months after treatment.

Men should use effective contraception during treatment with DBL Cisplatin Injection and for at least 4 months after treatment.

DBL Cisplatin Injection may affect male and female fertility. Check with your doctor for advice on fertility preservation before you begin treatment.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

DBL Cisplatin injection has been shown to pass into breast milk.

Women should not breastfeed during treatment with DBL Cisplatin Injection and for at last 1 month after treatment.

3. What if I am taking other medicines?

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

Some medicines may affect or be affected by DBL Cisplatin Injection. These include:

- some medicines to treat bacterial infections, e.g. gentamicin
- some medicine to treat fungal infections e.g. amphotericin B
- some medicine to treat cancer, e.g. ifosfamide, etoposide, paclitaxel, bleomycin
- methotrexate, a medicine used to treat some forms of arthritis, psoriasis and cancer
- medicine to reduce the amount of water in the body e.g. loop diuretics like furosemide
- medicine to treat gout e.g. allopurinol, colchine, probenecid, sulfinpyrazone
- medicine to prevent seizures/fits e.g. phenytoin
- blood thinners e.g. coumarins, warfarin
- lithium, used to treat bipolar disorder or schizophrenia.

Check with your doctor, nurse or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Cisplatin Injection.

4. How is DBL Cisplatin Injection given?

How is DBL Cisplatin Injection given

 You will be given DBL Cisplatin Injection as a slow injection (drip) into a vein.

How much will be given

 Your doctor will decide how much DBL Cisplatin Injection you will be given and how long you will be given it.

If you are given too much too much DBL Cisplatin Injection

As DBL Cisplatin Injection doses are carefully worked out and given by a doctor experienced in its use and who will monitor you during treatment, it is extremely unlikely that you will be given too much.

5. What should I know during treatment with DBL Cisplatin Injection?

Things you should do

Drink plenty of water prior to and after your treatment with DBL Cisplatin injection to ensure you are well hydrated as this may help to protect the kidneys.

Keep all of your doctor's appointments and attend any tests as directed, as treatment with DBL Cisplatin Injection requires your doctor to monitor your kidneys, liver, naturally occurring chemicals in your blood and blood cells.

During treatment with DBL Cisplatin Injection you may be at increased risk of bleeding, bruising and infection. Care should be taken to minimise cuts, impacts or exposure to infection.

Inform your doctor immediately if you experience:

- problems with your hearing or a buzzing/ringing or other noise in your ears
- abnormal bruising or bleeding, including in your urine/ wee, bowel motion/poo, or vomit
- signs of infection such as fever or chills
- signs of anaemia such as shortness of breath and dizziness
- severe vomiting that will not stop
- swelling of the face, wheezing, shortness of breath, skin rash or itchiness

- chest pain
- muscle spasms/cramps, which may also have numbness/tingling
- problems with your vision
- fits/seizures.

Discuss any dental work you feel may be required with your doctor before visiting your dentist.

Remind any doctor, nurse, dentist, surgeon, anaesthetist, or pharmacist you visit that you are being treated with DBL Cisplatin Injection.

Things you should not do

Avoid taking aspirin as it may increase the risk of bleeding in the mouth, throat, stomach and gut.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DBL Cisplatin Injection affects you.

Drinking alcohol

Alcohol should be avoided as it may increase the risk of bleeding in the mouth, throat, stomach and gut.

Looking after the medicine

DBL Cisplatin Injection will be stored appropriately at the hospital.

Getting rid of any unwanted medicine

The hospital staff will dispose of any leftover DBL Cisplatin Injection.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
 hiccups diarrhoea loss of appetite, weight loss hair loss, especially of the scalp feeling tired or weak loss of taste aches or pains red, raised or itchy skin rash 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Side effects	What to do
sore mouth or mouth ulcers	
 abnormal paleness, or lack of colour of the skin shaking or tremors, foot spasms, muscle cramps or twitching 	Speak to your doctor as soon as possible if you notice any of these side effects.
 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 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
 signs of an infection such as a fever, fatigue, chills, a sore throat, aches and pains or coughing pain, swelling, or redness around the injection site bursts of pain that run down the back into the arms and legs 	

Side effects What to do severe nausea and vomiting. reduced urination, joint pain, swelling of feet or lower legs, pain in the lower back or side, headache, seizures, slurred speech and loss of memory, confusion problems hearing or ringing or abnormal sounds in the ears eye pain, blurring or other changes in your vision problems with movement or reduced reflexes, and leg weakness 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

Side effects	What to do
pinpoint red spots on the skin	
 changes in the rhythm or rate of the heartbeat, tightness or pain of the chest, neck, back or arms 	
 shortness of breath, chest pain or coughing yellowing of the skin, eyes or mouth, dark urine/wee 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/safety/reporting-problems.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What DBL Cisplatin Injection contains

Active ingredient	Cisplatin
(main ingredient)	
Other ingredients	Mannitol
(inactive ingredients)	Sodium chloride
	Water for injections

This medicine should not be used if you are allergic to any of these ingredients.

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

What DBL Cisplatin Injection looks like

DBL Cisplatin Injection is a clear colourless to pale yellow solution (AUST R 47275 and AUST R 47276).

Who distributes DBL Cisplatin Injection

Pfizer Australia Pty Ltd Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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