DBL™ Docetaxel Concentrated Injection

Consumer Medicine Information (CMI) summary

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

1. Why am I being treated with DBL Docetaxel Concentrated Injection?

DBL Docetaxel Concentrated Injection contains the active ingredient docetaxel. Docetaxel is used to treat breast, non-small cell lung, ovarian, prostate and head and neck cancer. For more information, see Section 1. Why am I being treated with DBL Docetaxel Concentrated Injection? in the full CMI.

2. What should I know before I am treated with DBL Docetaxel Concentrated Injection?

You will not be given DBL Docetaxel Concentrated Injection if you have ever had an allergic reaction to it or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have liver problems, kidney problems, gout, epilepsy or any other medical conditions, take any other medicines, have an addiction to alcohol or are pregnant or plan to become pregnant or are breastfeeding. Make sure you take any other medicine your doctor may give prior to treatment to prevent or reduce side effects. For more information, see Section 2. What should I know before I am treated with DBL Docetaxel Concentrated Injection? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Docetaxel Concentrated Injection and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given DBL Docetaxel Concentrated Injection?

DBL Docetaxel Concentrated Injection should only be administered by trained healthcare professionals, with appropriate handling, in a hospital or clinic environment. More instructions can be found in Section <u>4. How will I be given DBL Docetaxel Concentrated Injection?</u> in the full CMI.

5. What should I know while being treated with DBL Docetaxel Concentrated Injection?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are being treated with DBL Docetaxel Concentrated Injection. Keep follow up appointments with your doctor. Reduce your risk of infection or bleeding. Inform your doctor or nurse immediately if you notice: swelling in the feet or legs; weight gain; rash, tight chest or problems breathing, back pain, shortness of breath, fever/chills; abnormal bleeding or bruising; stomach pain; severe diarrhoea; changes in hearing or vision; red skin, pustules, blisters or peeling; severe pain, tingling, numbness, balance problems. 	
Driving or using machines	Be careful driving or operating machinery until you know how DBL Docetaxel Concentrated Injection affects you.	
Looking after your medicine		
Alcohol	DBL Docetaxel Concentrated Injection contains alcohol.	

For more information, see Section <u>5. What should I know while being treated with DBL Docetaxel Concentrated Injection?</u> in the full CMI.

6. Are there any side effects?

Side effects include: joint/body/muscle pain/swelling/tenderness/weakness; skin/hair/nail/eye/ear problems; stomach pain; feeling sick; vomiting/diarrhoea/constipation; high temperature; difficulty eating; tiredness; burning/tingling in extremities; sudden allergy signs; skin redness with pimples/fluid/pus; convulsions/fits/seizures; vomiting blood/coffee ground looking material; bleeding from back passage, black/sticky bowel motions; bloody diarrhoea; difficulty breathing, rapid and/or shallow breathing; sudden swelling of the leg/arm; pain/pressure/tightness in chest/arms/neck/jaw/back that may occur with nausea/dizziness/cold sweats; fainting; fever with diarrhoea/vomiting/painful cramping.

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

DBL™ Docetaxel Concentrated Injection

Active ingredient(s): docetaxel (doe-suh-TAK-sel)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- 1. Why am I being treated with DBL Docetaxel Concentrated Injection?
- 2. What should I know before I am treated with DBL Docetaxel Concentrated Injection?
- 3. What if I am taking other medicines?
- 4. How will I be given DBL Docetaxel Concentrated Injection?
- <u>5.</u> What should I know while being treated with DBL Docetaxel Concentrated Injection?
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details

1. Why am I being treated with DBL Docetaxel Concentrated Injection?

DBL Docetaxel Concentrated Injection contains the active ingredient docetaxel. DBL Docetaxel Concentrated Injection belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called anti-cancer or chemotherapy medicines. It works by stopping cells from growing and multiplying.

DBL Docetaxel Concentrated Injection is used to treat:

- breast cancer
- non-small cell lung cancer
- ovarian cancer
- prostate cancer
- head and neck cancer.

2. What should I know before I am treated with DBL Docetaxel Concentrated Injection?

Warnings

Do not use DBL Docetaxel Concentrated Injection if:

 you are allergic to docetaxel, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions including
- 1. liver problems

- 2. blood disorder with a reduced number of white blood
- 3. kidney problems
- 4. epilepsy
- 5. addiction to alcohol or a heavy drinker.
- take any medicines for any other condition.

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 6. Are there any side effects?

Pregnancy and breastfeeding

This medicine should not be used if you are pregnant or intend to become pregnant.

You should use a reliable method of contraception during treatment and for at least 2 months after your last dose.

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

Do not breastfeed during treatment with this medicine and for 1 week after your last dose.

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

Males

If you are with a female partner who can become pregnant, you should use a reliable method of contraception during treatment with DBL Docetaxel Injection and for at least 4 months after your last dose.

You should seek advice from your doctor on preserving sperm before starting treatment.

Genetic Counselling

Both males and females should discuss the need for individual genetic counselling with their doctor if you decide to have a child 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 interfere with DBL Docetaxel Concentrated Injection and affect how it works.

These include:

- other medicines used to treat cancer, radiation therapy or any other treatment which lowers your immune system, including ciclosporin, vinorelbine, vinblastine
- medicines used to treat bacterial infections (antibiotics), including erythromycin and clarithromycin

- medicines used to treat fungal infections, including ketoconazole, itraconazole and voriconazole
- nifedipine, a medicine used to treat high blood pressure and angina
- clofibrate, a medicine used to lower cholesterol
- medicines called corticosteroids such as dexamethasone
- medicines used to treat people with epilepsy, including phenobarbitone
- medicines used to treat or prevent HIV or Hepatitis C viral infections, including ritonavir.

These medicines may be affected by DBL Docetaxel Concentrated Injection or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

4. How will I be given DBL Docetaxel Concentrated Injection?

Before you are treated with your docetaxel infusion

Your doctor should:

- prescribe you an oral corticosteroid (e.g. dexamethasone) to help stop or reduce the severity of certain side effects. For breast, lung, ovarian and head and neck cancer, this medicine is usually taken for three days (one day before, the day of and the day after your infusion). These medicines are very important. For prostate cancer, this is usually taken on the day of the infusion (12 hours, 3 hours and 1 hour before your infusion).
- test your blood to see how many white blood cells you have. If they are too low, your infusion may be delayed.
- test your blood for levels of liver enzymes. If these levels are high your doctor may reduce your dose or decide you should not have a docetaxel infusion at that time.

Ask your doctor if you have any questions on these medicines or tests.

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight, kidney function and other chemotherapy medicines you are being treated with.

Docetaxel may be given alone or in combination with other drugs.

Several courses of docetaxel therapy may be needed depending on your response to treatment. Additional treatment may not be repeated until your blood cell numbers return to acceptable levels.

Ask your doctor if you want to know more about the dose of docetaxel you will receive.

How is it given

DBL Docetaxel Concentrated Injection is given as an infusion (slow drip) into your veins, over 1 hour.

Docetaxel is usually given every 3 weeks. This is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

If you are given too much DBL Docetaxel Concentrated Injection

As DBL Docetaxel Concentrated Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any severe side effects after being given DBL Docetaxel Concentrated Injection, you should immediately:

- contact your doctor, or
- go to the Emergency Department at your nearest hospital, or
- phone the Poisons Information Centre (by calling 13 11 26).

You may need urgent medical attention.

5. What should I know while being treated with DBL Docetaxel Concentrated Injection?

Things you should do

Keep follow up appointments with your doctor.

It is important to have your follow-up doses/cycles/infusions of docetaxel at the appropriate times to get the best effects from your treatment.

Your doctor may want to check your blood pressure and do some blood and other tests from time to time to check on your progress and detect any unwanted side effects.

If you are about to start on any new medicine, tell your doctor, dentist or pharmacist that you are receiving DBL Docetaxel Concentrated Injection.

If you plan to have surgery that needs a general anaesthetic, tell your doctor that you are receiving DBL Docetaxel Concentrated Injection.

DBL Docetaxel, Concentrated Injection can lower the number of white blood cells and platelets in your blood. This means that you have an increased chance of getting an infection or bleeding.

The following precautions should be taken to reduce your risk of infection or bleeding:

- avoid people who have infections. Check with your doctor immediately if you think you may be getting an infection, or if you get a fever, chills, cough, hoarse throat, lower back or side pain or find it painful or difficult to urinate.
- wash your hands frequently with soap and water, especially before eating, after using the bathroom, and after touching high-touch surfaces
- be careful when using a toothbrush, toothpick or dental floss. Your doctor, dentist, nurse or pharmacist may recommend other ways to clean your teeth and

- gums. Check with your doctor before having any dental work.
- be careful not to cut yourself when you are using sharp objects such as a razor or nail cutters
- avoid contact sports or other situations where you may bruise or get injured.

If you notice swelling in the feet and legs or a slight weight gain, inform your doctor or nurse.

Docetaxel may cause fluid retention which means the body is holding extra water. If this fluid retention is in the chest or around the heart it can be life threatening. In most cases, fluid retention will go away within weeks or months after your treatments are completed.

Inform your doctor or nurse if you notice any of the following:

- flushing, rash (with or without itchiness), tight chest, back pain, shortness of breath, fever, chills
- abnormal bleeding or bruising
- abdominal pain or tenderness or severe diarrhoea
- changes in hearing or abnormal sounds in the ears
- changes in vision
- painful red areas of the skin, pustules or blisters, or skin peeling
- problems breathing
- numbness, tingling in the hands or feet and loss of reflexes
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

Call your doctor straight away if you become pregnant while you are being treated with DBL Docetaxel Concentrated Injection.

Remind any doctor, dentist or pharmacist you visit that you are being treated with DBL Docetaxel Concentrated Injection.

Driving or using machines

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

DBL Docetaxel Concentrated Injection may cause dizziness, light-headedness, tiredness, and drowsiness in some people. Make sure you know how you react to docetaxel before you drive a car, operate machinery, or do anything else that could be dangerous and do not do so if not safe. DBL Docetaxel Concentrated Injection also contains alcohol, which may affect the ability to safely drive or use machinery.

Alcohol

DBL Docetaxel Concentrated Injection contains ethanol (alcohol).

The alcohol content in this medication is harmful to those who suffer from alcohol dependency. The alcohol content in this medication should be considered in patients suffering from epilepsy or liver disease.

Speak to your doctor if you may drink alcohol while having treatment with DBL Docetaxel Concentrated Injection.

Looking after your medicine

DBL Docetaxel Concentrated Injection will be stored in the pharmacy or on the ward.

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

about side effects.		
		What to do
• • • • • • • • • • • • • • • • • • • •	irritation, pain, swelling or colouring around the needle during infusion stomach pain or discomfort feeling sick, upset stomach or vomiting mild diarrhoea constipation difficult or painful swallowing, sore throat indigestion, heartburn dry mouth nose bleeds, runny nose food taste different, especially metallic whitening or darkening of the skin or nails loosening of the nails unusual hair loss or thinning joint pain or swelling aching muscles, muscle tenderness, swelling or weakness not caused by exercise unusual tiredness or weakness mild swelling of hands, ankles and feet weight gain/loss pins and needles or a burning or tingling feeling in hands or feet redness or rash around previous radiation site (if you have had radiotherapy) back pain loss of, or irregular, periods (menstruation) decreased appetite headache dizziness temporary visual disturbances,	What to do Speak to your doctor, nurse or pharmacist if you have any of these less serious side effects and they worry you.
	or feeling that you are about to faint, which mostly occur when you are being infused with docetaxel.	

		What to do
•	high temperature or an infection	Tell your doctor
•	frequent infections with fever,	as soon as
	severe chills, sore throat or	possible if you
	mouth ulcers - especially 5-7	notice any of
	days after receiving a docetaxel	these serious
	infusion	side effects.
•	sore red mouth or vagina or	
	swelling in these areas	
•	severe diarrhoea	
•	tiredness, headaches, being	
	short of breath when exercising,	
	dizziness and looking pale	
•	coughing	
•	change in the rhythm or rate of	
	your heart beats (palpitations)	
•	muscle pain or cramps	
•	flushed, dry skin	
•	skin numbness or loss of feeling	
•	irritability and confusion	
•	passing little or no urine,	
	drowsiness, nausea, vomiting	
	and breathlessness	
•	yellowing of the skin or eyes,	
	also called jaundice	
•	flaking or peeling of the skin	
•	red, scaly patches of the skin	
	especially around the cheeks	
	and nose	
•	raised lumps on the skin which	
	looks like scalding	
•	hardening of the skin	
•	skin that is red and warm	
•	excessive watery discharge from	
	the eyes	
•	trouble with your hearing, or	
	some loss of hearing or	
	abnormal sounds in the ears	
•	sudden and severe swelling or	
	pain in the joints or rash	
•	blurry or "wavy" vision or	
	disturbances to colour vision	
•	leg pain, tenderness or swelling.	
		1

	What to do
 sudden signs of allergy such as rash, itching, hives on the skin, swelling of the face, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing redness of the skin studded with pimples containing fluid or pus convulsions, fits or seizures 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of
 hallucinations or delirium ulcer in the stomach or intestine vomiting blood or material that 	these very serious side effects.

bleeding from the back passage, black sticky bowel motions or bloody diarrhoea difficulty in breathing, rapid and/or shallow breathing sudden swelling of the leg/arm which may be due to blood clots pain, pressure or tightness in the chest, arms, neck, jaw or back that may occur together with nausea, dizziness or cold sweats fainting fever with diarrhoea and or vomiting, painful cramping.		What to do
	 black sticky bowel motions or bloody diarrhoea difficulty in breathing, rapid and/or shallow breathing sudden swelling of the leg/arm which may be due to blood clots pain, pressure or tightness in the chest, arms, neck, jaw or back that may occur together with nausea, dizziness or cold sweats fainting fever with diarrhoea and or 	

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.

These side effects may differ when using docetaxel in combination with another chemotherapy agent.

Please consult your doctor for possible side effects that may be caused by using docetaxel with another chemotherapy agent.

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 Docetaxel Concentrated Injection contains

Active ingredient	Docetaxel
(main ingredient)	
Other ingredients	Ethanol
(inactive	Citric acid
ingredients)	Polysorbate 80
	Macrogol 300
Potential allergens	DBL Docetaxel Concentrated Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What DBL Docetaxel Concentrated Injection looks like

DBL Docetaxel Concentrated Injection is a clear, colourless to pale yellow solution in single dose vials, which is diluted prior to intravenous administration.

DBL Docetaxel, Concentrated Injection is available in the following strengths:

- 20 mg/2 mL vial AUST R 163802
- 80 mg/8 mL vial AUST R 163801
- 160 mg/16 mL vials AUST R 163803

Who distributes DBL Docetaxel Concentrated Injection

Pfizer Australia Pty Ltd Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in October 2025.

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