DBL™ VINBLASTINE INJECTION

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. Speak to your doctor if you are worried about being given this medicine.

1. Why am I being given DBL VINBLASTINE Injection?

DBL VINBLASTINE Injection contains the active ingredient vinblastine sulfate. DBL VINBLASTINE Injection is used to treat some types of cancers. For more information, see Section 1. Why am I receiving DBL VINBLASTINE Injection? in the full CMI.

2. What should I know before being given DBL VINBLASTINE Injection?

Do not use if you have ever had an allergic reaction to DBL VINBLASTINE Injection or any of the ingredients listed at the end of the CMI. Tell your doctor if you have an infection or high temperature, liver disease, chicken pox, shingles, gout or kidney stones. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. You must not be

given DBL VINBLASTINE Injection if you are pregnant or intend to become pregnant. For more information, see Section 2. What should I know before being given DBL VINBLASTINE Injection? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL VINBLASTINE 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 am I given DBL VINBLASTINE Injection?

DBL VINBLASTINE Injection is given by a slow injection (drip) into a vein. DBL VINBLASTINE Injection will be given to you by a doctor or nurse. For more information, see Section 4. How am I given DBL VINBLASTINE Injection? in the full CMI.

5. What should I know while being given DBL VINBLASTINE Injection?

Things you should do

 Tell your doctor if you have any other medical conditions or if you take any other medicines, and remind them you

	 are being given DBL VINBLASTINE Injection. Tell your doctor immediately if you become pregnant while being treated with DBL VINBLASTINE Injection. Tell your doctor if you experience any signs of infection, such as fever, sore throat, unusual bleeding or bruising.
Things you should not do	 Do not receive DBL VINBLASTINE Injection if you have had an allergic reaction to vinblastine sulfate or any of the ingredients listed at the end of this leaflet.
Driving or using machines	 Be careful driving or operating machinery until you know how DBL VINBLASTINE Injection affects you. DBL VINBLASTINE Injection may cause dizziness, drowsiness or affect coordination.
Drinking alcohol	There is no information as to how DBL

	VINBLASTINE Injection interacts with alcohol
Looking after your medicine	DBL VINBLASTINE Injection is stored appropriately in the pharmacy or on the hospital ward.

For more information, see Section <u>5. What should I know while using DBL VINBLASTINE Injection?</u> in the full CMI.

6. Are there any side effects?

DBL VINBLASTINE Injection can lower the number of white blood cells and platelets in your blood, increasing your chance of bleeding or getting an infection. DBL VINBLASTINE Injection side effects are generally dose related and include nausea, vomiting, constipation, diarrhoea, drowsiness, dizziness, general weakness. Other side effects include hair loss, weight loss, problems with ejaculation, lack of menstrual periods, blisters on skin, ringing in the ears, problems with balance and depressed mood. Serious side effects include infections with fever and severe chills, signs of an allergic reaction, severe pain, redness, swelling, discolouration, blistering, warmth or oozing at the site of injection, unusual bleeding or bruising, pressure, tightness or pain in chest or arms, and numbness or tingling in fingers, toes, arms or legs or trouble walking. 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™ VINBLASTINE INJECTION

Active ingredient: vinblastine sulfate

Consumer Medicine Information (CMI)

This leaflet provides important information about being given DBL VINBLASTINE 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 using this medicine against the benefits they expect it will have for you.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given DBL VINBLASTINE Injection.

Where to find information in this leaflet:

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

1. Why am I being given DBL VINBLASTINE Injection?

DBL VINBLASTINE Injection contains the active ingredient vinblastine sulfate.

DBL VINBLASTINE Injection belongs to a group of medicines called cytotoxic medicines that work by killing cancer cells and stopping cancer cells from growing and multiplying. These are also known as chemotherapy medicines. DBL VINBLASTINE Injection is classified as a 'vinca alkaloid' type of cytotoxic and is used to treat some types of cancers including

- Hodgkin's disease (Stages III and IV)
- Advanced testicular cancer
- Lymphocytic lymphoma
- Histiocytic lymphoma
- Advanced mycosis fungoides
- Kaposi's sarcoma
- Histiocytosis X
- Choriocarcinoma
- Breast cancer

DBL VINBLASTINE may be given alone or together with other medicines in the treatment of cancer.

2. What should I know before being given DBL VINBLASTINE?

Warnings

Do not receive DBL VINBLASTINE if:

- You are allergic to vinblastine, or any of the ingredients listed at the end of this leaflet.
 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.

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

- You have any condition with a reduced number of red blood cells, white blood cells or platelets.
- You have an infection or high temperature.

Your doctor may decide to delay your treatment until the infection has gone. A mild illness, such as a cold, is not usually a reason to delay treatment.

Females: you must not be given DBL VINBLASTINE Injection if you are pregnant or intend to become pregnant.

Like most cytotoxic medicines, this medicine is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

DBL Vinblastine Injection may cause birth defects if either the male or the female is undergoing treatment at the time of conception.

It is recommended that you use an appropriate method of birth control while you are being treated with this medicine and for at least 7 months after your last dose. Your doctor will discuss this with you.

You should not breast feed while you are being given and for at least 1 week after your last dose with DBL VINBLASTINE Injection.

It is not known whether this medicine passes into breast milk. Therefore, breastfeeding is not recommended as there is a possibility that the breast-fed baby may be affected.

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

It is recommended that you use an appropriate method of birth control while you are being treated with this medicine and for at least 4 months after your last dose. Your doctor will discuss this with you.

DBL VINBLASTINE Injection may cause birth defects if either the male or the female is undergoing treatment at the time of conception.

If you are not sure whether any of the above conditions apply to you, ask your doctor.

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - Liver disease.
 - Chicken pox (including a recent exposure)
 - Shingles
 - Gout
 - Kidney stones
 - History of infection
- 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 <u>6</u>. Are there any side effects?

3. What if I am taking other medicines?

You should not receive certain types of vaccines while you are receiving treatment with DBL VINBLASTINE Injection.

Tell your doctor if you plan to receive any vaccinations while being given DBL VINBLASTINE Injection.

Tell your doctor or pharmacist if you are taking or using 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 VINBLASTINE Injection and affect how it works.

Some medicines and DBL VINBLASTINE Injection may interfere with each other. These include:

- some medicines used to treat infections, such as erythromycin, amphotericin B, flucytosine and chloramphenicol
- medicines that suppress your immune system, such as azathioprine, interferon and zidovudine
- colchicine, a medicine used to treat gout
- phenytoin, a medicine used to treat epilepsy (fits)
- some other cytotoxic agents such as cisplatin, bleomycin and mitomycin
- some vaccines (ask your doctor).

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

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

4. How am I given DBL VINBLASTINE Injection?

DBL VINBLASTINE Injection is given to you by a healthcare professional into a vein (intravenously). It may be given either as a slow injection or as an infusion (drip) into a vein.

How much will I be given

Your doctor will decide how much DBL VINBLASTINE Injection you should receive. This depends on your condition and other factors, such as your height, weight, and other chemotherapy medicines you are being given.

DBL VINBLASTINE Injection may be given alone or in combination with other drugs.

Several courses of DBL VINBLASTINE Injection 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 and any uncontrolled effects have been controlled.

Ask your doctor if you want to know more about the dose of DBL VINBLASTINE Injection you receive.

How often will I be given it

DBL VINBLASTINE Injection is usually given once a week. Each treatment is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

If you receive too much DBL VINBLASTINE Injection

Symptoms of an overdose with DBL VINBLASTINE Injection include the side effects listed below in the 'Side Effects' section but are usually of a more severe nature.

As DBL VINBLASTINE Injection is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. If you experience any side effects after being given DBL VINBLASTINE Injection, tell your doctor immediately.

5. What should I know while being given DBL VINBLASTINE Injection?

Tell your doctor or nurse if you have any concerns before, during or after the administration of DBL VINBLASTINE Injection.

Things you should do

Use effective contraceptive methods to prevent pregnancy during treatment with DBL VINBLASTINE Injection and for at least 7 months after your last dose for women and 4 months after your last dose for men.

Females: If you become pregnant while being treated with DBL VINBLASTINE Injection, tell your doctor immediately.

Males: If your partner becomes pregnant while being treated with DBL VINBLASTINE Injection, tell your doctor immediately.

Tell all doctors, dentists and pharmacists who are treating you that you are receiving DBL VINBLASTINE Injection.

Keep all your doctors' appointments so your progress can be checked.

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.

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

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given DBL VINBLASTINE Injection.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given DBL VINBLASTINE Injection.

DBL VINBLASTINE 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 with 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.
- 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 toothbrush, dental floss or toothpick. 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 done.
- 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 get bruised or injured.

Your body breaks down DBL VINBLASTINE Injection and uses it to fight cancer. The breakdown products may be excreted in body fluids and waste, including blood, urine, faeces, vomitus and semen.

In general, precautions to protect other people should be taken while you are receiving chemotherapy and for one week after the treatment period by:

- Flushing the toilet twice to dispose of any body fluids and waste.
- Wearing gloves to clean any spill of body fluid or waste. Use paper towels or old rags, a strong solution of non-bleaching detergent and large amounts of water to mop up the spill. Discard the towels or rags into a separate waste bag and dispose of fluids in the toilet.
- Wash linen or clothing that is heavily contaminated by body fluids or waste separately from other items. Use a strong solution of non-bleaching detergent and large amounts of water.
- Place soiled disposable nappies and other pads in a plastic bag, seal and dispose into the garbage.
- For sexual intercourse, use a barrier method such as a condom.

Call your doctor straight away if you:

 Become pregnant while receiving DBL VINBLASTINE Injection

Things you should not do

 You should not breast feed while you are being given and for at least 1 week after your last dose with DBL VINBLASTINE Injection. It is not known whether DBL VINBLASTINE Injection crosses into human milk. Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting with a pharmacist.

Driving or using machines

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

This medicine may cause dizziness, drowsiness or affect coordination. Make sure you know how you react to this medicine before you drive a car, operate machinery, or do anything else that requires you to be alert.

Drinking alcohol

Tell your doctor if you drink alcohol.

There is no information on how DBL VINBLASTINE Injection and alcohol may interact. Be careful when drinking alcohol as DBL VINBLASTINE Injection may cause dizziness in some people.

Looking after your medicine

DBL VINBLASTINE Injection will be stored in the pharmacy or on the hospital 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.

Common side effects

Side effects	What to do
Injection site reactionsPain, redness or	Speak to your doctor if you have any of these
swelling, General disorders	side effects and they worry you.
 Dizziness or lightheadedness, 	
 Drowsiness, fatigue (feeling tired) and/or feeling weak 	
Hair lossWeight loss	

Side effects	What to do
 Ringing in the ears, or hearing loss 	
 Depressed mood 	
Nervous system	
Problems with balance	
Stomach related issues	
 Nausea (feeling sick) or vomiting, stomach pain or discomfort. Constipation or diarrhoea 	
Reproductive issues	
 Problems with ejaculation, such as decreased amount of semen released during sex 	
Lack of menstrual periods	

Serious side effects throughout treatment

Side effects	What to do
 Allergic type reactions Shortness of breath, wheezing or difficulty breathing Swelling of the face, lips, tongue or other parts of the body Rash, itching or hives on skin 	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.
 Infections Signs of infection, such as a fever, sore throat and chills Injection site reactions 	
 Severe pain, redness, swelling, discolouration, blistering, warmth or oozing at the site of injection 	
Blood disorders	
 Signs and symptoms suggestive of a bleeding disorder such as unusual bleeding or bruising, black, tarry 	

Side effects	What to do
stools, blood in the urine or stools, or red pinpricks under the skin	
Heart related issues	
 Pressure, tightness or pain in the chest or arms that may spread to the neck, jaw or back 	
Stomach issues	
 Mouth ulcers and/or anal ulceration 	
Nervous system	
 Numbness or tingling in fingers, toes, arms or legs, trouble walking Difficulty swallowing Blurred or loss of vision Slurred speech, loss of speech Loss of memory, confusion Convulsions (fits) 	
Convulsions (fits)Musculoskeletal issues	
Jaw or bone pain	

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.

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/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 VINBLASTINE Injection contains

Active ingredient	Vinblastine sulfate
(main ingredient)	
Other ingredients	Sodium chloride
(inactive ingredients)	Water for injections

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

What DBL VINBLASTINE Injection looks like

DBL VINBLASTINE Injection is a clear, colourless solution.

DBL VINBLASTINE Injection 10 mg/10 mL ONCO-TAIN vial AUST R 16309

Who distributes DBL VINBLASTINE Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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