DBL[™] Vinblastine Injection

Vinblastine Sulfate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about 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 being given DBL Vinblastine Injection 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 in a safe place.

You may need to read it again.

What DBL Vinblastine Injection is used for

DBL Vinblastine Injection is used to treat some types of cancers.

This medicine works by killing cancer cells and stopping cancer cells from growing and multiplying.

DBL Vinblastine Injection belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these being called chemotherapy medicines.

DBL Vinblastine Injection is classified as a 'vinca alkaloid' type of cytotoxic.

It may be given alone, or used in combination with other medicines to treat cancer.

Your doctor may have prescribed DBL Vinblastine Injection for another reason.

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

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

Before you are given DBL Vinblastine Injection

When you must not be given it

You must not be given DBL Vinblastine Injection if you if you have an allergy to:

- · vinblastine
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to DBL Vinblastine Injection 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.

You must not be given DBL Vinblastine Injection if you have any of the following conditions:

- any condition with a reduced number of red blood cells, white blood cells or platelets
- a bacterial infection.

Tell your doctor if 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.

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 some kind of birth control while you are being treated with this medicine. Your doctor will discuss this with you.

You should not breast-feed while you are being treated 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 breastfed baby may be affected.

If you are not sure whether you should start treatment with DBL Vinblastine Injection, talk to your doctor or pharmacist.

Before you are given it

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

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

- · liver disease
- chicken pox (including a recent exposure)
- shingles
- gout
- kidney stones.

If you have not told your doctor about any of the above, tell them before you are given DBL Vinblastine Injection.

Taking other medicines

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

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.

How DBL Vinblastine Injection is given

How much is given

Your doctor will decide what dose you will 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 it is given

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

DBL Vinblastine Injection is only given into a vein (intravenously). It may be given either as a slow injection or as an infusion (drip) into a vein.

How long it is given for

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 (overdose)

As DBL Vinblastine Injection is most likely to be given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DBL Vinblastine Injection. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are being given DBL Vinblastine Injection

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

Things you must do

Be sure to keep all your doctor's 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.

Keep follow up appointments with your doctor.

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

Tell any other doctors, dentists, and pharmacists who are treating

you that you are being given DBL Vinblastine Injection.

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.

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

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.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given DBL Vinblastine Injection. Like other medicines that treat cancer, DBL Vinblastine Injection may have unwanted side effects, some of which may be serious. You may need medical treatment if you get some of the side effects.

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
- diarrhoea or constipation
- problems with ejaculation, such as decreased amount of semen released during sex
- · lack of menstrual periods
- blisters on the skin
- hair loss
- · weight loss
- drowsiness, dizziness and general weakness.

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

- ringing in the ears (tinnitus), hearing loss
- problems with balance
- · depressed mood

Tell your doctor immediately or go to the Accident and Emergency department of your nearest hospital if you notice any of the following:

- signs of an infection, such as sore throat, fever or chills
- signs of an allergic reaction, such as those listed at the start of this leaflet
- severe pain, redness, swelling, discolouration, blistering, warmth or oozing at the site of injection
- any signs of unusual bleeding or bruising, such as black, tarry stools, blood in the urine or stools, or red pinpricks under the skin
- pressure, tightness or pain in the chest or arms that may spread to the neck, jaw or back

- numbness or tingling in fingers, toes, arms or legs, trouble walking
- · difficulty swallowing
- blurred of loss of vision
- · slurred speech, loss of speech
- · loss of memory, confusion
- mouth ulcers and/or anal ulceration
- severe stomach or abdominal pain
- · jaw or bone pain
- · convulsions (fits).

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

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

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

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

You may not experience any of them.

The benefits and side effects of DBL Vinblastine Injection may take some time to occur. Therefore, even after you have finished receiving your DBL Vinblastine Injection treatment you should tell your doctor immediately if you notice any of the side effects listed in this section.

After being given DBL Vinblastine Injection

Storage

DBL Vinblastine Injection will be stored in the pharmacy or on the ward. The injection is kept in the refrigerator where the temperature stays between 2 and 8°C. It should be protected from light.

Product description

What it looks like

DBL Vinblastine Injection is a clear, colourless solution.

Ingredients

Active ingredient:

· vinblastine sulfate

Other ingredients:

- · sodium chloride
- · Water for injections

DBL Vinblastine Injection 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 Vinblastine Injection is available in the following strength:

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

TM = Trademark

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