

DBL™ Vincristine Sulfate Injection

Consumer Medicine Information (CMI) summary

The [full CMI](#) 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 given DBL Vincristine Sulfate Injection?

DBL Vincristine Sulfate Injection contains the active ingredient vincristine sulfate. DBL Vincristine Sulfate Injection is used to treat certain cancers, including acute leukaemia, Hodgkin's disease, non-Hodgkin's disease, rhabdomyosarcoma, neuroblastoma, Wilms' tumour, bone cancer, mycosis fungoides, Ewing's sarcoma, uterine or cervical cancer, breast cancer, malignant melanoma, lung cancer, gynaecological childhood tumours.

For more information, see Section [1. Why am I being given DBL Vincristine Sulfate Injection?](#) in the full CMI.

2. What should I know before receiving DBL Vincristine Sulfate Injection?

Do not use if you have ever had an allergic reaction to vincristine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions such as the demyelinating form of Charcot-Marie-Tooth-Syndrome, take any other medicines, if you are currently receiving or have received radiation therapy to areas that include the liver or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before receiving DBL Vincristine Sulfate Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DBL Vincristine Sulfate 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 is DBL Vincristine Sulfate Injection given?

- Your doctor will decide what dose, how often and how long you will receive this medicine.
- DBL Vincristine Sulfate Injection is given as a slow injection into a vein and must only be given by a doctor or nurse.

More instructions can be found in Section [4. How is DBL Vincristine Sulfate Injection given?](#) in the full CMI.

5. What should I know while receiving DBL Vincristine Sulfate Injection?

Things you should do	• Remind any doctor, dentist, nurse or pharmacist you visit that you are receiving this medicine. • DBL Vincristine Sulfate Injection can increase your risk of infection and bleeding. It can be excreted in your body fluids and waste. Information on how to reduce your risk and protect others can be found in the full CMI.
Things you should not do	• Do not have any immunisations or vaccinations without your doctor's approval and for up to 12 months after you stop treatment.
Driving or using machines	• Be careful driving or operating machinery until you know how vincristine affects you. • This medicine may cause dizziness, tiredness or affect vision or movement in some people.
Looking after your medicine	• DBL Vincristine Sulfate Injection will be stored in the pharmacy or on the ward. • It must be kept in a refrigerator, where the temperature stays between 2-8°C.

For more information, see Section [5. What should I know while receiving DBL Vincristine Sulfate Injection?](#) in the full CMI.

6. Are there any side effects?

Side effects of this medicine include: hair loss; diarrhoea, nausea, vomiting; loss of appetite, weight loss; headache; unusual perspiration; increased sunburn; tingling or burning sensation; inflamed gums; impotence or reduced sexual drive; dizziness or light-headedness; constipation; loss of feeling, hearing or taste; difficulty walking; muscle wasting, aches or spasms; mouth ulcers; different urination frequency; jaw, bone, limb or back pain; vision problems; trouble sleeping, depression, nervousness, hallucinations, confusion or personality changes; tightness or pain in the chest, neck, back or arms and abnormal heartbeat; signs of allergy; difficulty breathing; signs of infection; unusual bleeding or bruising; abdominal or stomach cramps; abdominal pain or swelling, sudden weight gain; yellowing of the skin and eyes; loss of movement or coordination; fits. 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™ Vincristine Sulfate Injection

Active ingredient(s): vincristine sulfate

Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Vincristine Sulfate 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 Vincristine Sulfate Injection.**

Where to find information in this leaflet:

1. [Why am I being given DBL Vincristine Sulfate Injection?](#)
2. [What should I know before receiving DBL Vincristine Sulfate Injection?](#)
3. [What if I am taking other medicines?](#)
4. [How is DBL Vincristine Sulfate Injection given?](#)
5. [What should I know while receiving DBL Vincristine Sulfate Injection?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given DBL Vincristine Sulfate Injection?

DBL Vincristine Sulfate Injection contains the active ingredient vincristine sulfate. Vincristine sulfate belongs to a group of anticancer medicines called Vinca alkaloids. It is used for the treatment of various cancers. Vincristine stops the cancer cells growing and eventually kills them.

Since the growth of normal body cells may also be affected by vincristine, other effects may also occur (see Section [6. Are there any side effects?](#)).

DBL Vincristine Sulfate Injection is used to treat certain cancers. These cancers include:

- acute leukaemia
- Hodgkin's disease
- non-Hodgkin's disease
- rhabdomyosarcoma
- neuroblastoma
- Wilm's tumour
- bone cancer
- mycosis fungoides
- Ewing's sarcoma
- uterine or cervical cancer
- breast cancer
- malignant melanoma
- lung cancer
- gynaecological childhood tumours

Your doctor may have prescribed vincristine for another reason.

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

Vincristine is not addictive.

2. What should I know before receiving DBL Vincristine Sulfate Injection?

Warnings

Do not receive DBL Vincristine Sulfate Injection if:

- you are allergic to vincristine, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any of the Vinca alkaloids medicines e.g. vinblastine and vindesine.
- you suffer from demyelinating Charcot-Marie-Tooth-Syndrome. This is a type of hereditary nerve disease.
- you are receiving or have received radiation therapy to areas that include the liver.
- you are pregnant or intend to become pregnant.
- you are breast-feeding or plan to breast-feed.

Symptoms of an allergic reaction to vincristine 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.

If you are not sure whether you should be given DBL Vincristine Sulfate Injection, talk to your doctor or pharmacist.

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

- gout
- kidney stones
- liver problems or jaundice
- any infections, especially chicken pox or shingles
- nerve or muscle disease.

Check with your doctor if you 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

You must not be given DBL Vincristine Sulfate Injection if you are pregnant or intend to become pregnant.

Vincristine may affect your developing baby if you are given it during pregnancy.

It is recommended that you and your doctor discuss the need for vincristine treatment during pregnancy, and the possible risks and benefits of using vincristine during pregnancy.

Vincristine may cause birth defects if either the male or the female is undergoing treatment at the time of conception, or if the female is receiving vincristine during early pregnancy.

Women of childbearing potential should use effective contraception during treatment with DBL Vincristine Sulfate Injection and for at least 7 months after the last dose.

Male patients being treated with Vincristine Sulfate injection should use effective contraception during treatment and for at least 4 months after the last dose if their female partner is of child bearing potential.

Many cancer medicines can cause infertility. Your doctor should discuss this issue with you before you begin therapy with vincristine.

You should not be given DBL Vincristine Sulfate Injection if you are breast-feeding or plan to breast-feed.

It is not known whether vincristine passes into breast milk. Do not breastfeed while being treated with DBL Vincristine Sulfate Injection and for one month after the last dose.

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 and vincristine may interfere with each other. These include:

- other anti-cancer drugs e.g. bleomycin, methotrexate, doxorubicin, asparaginase, cis-platin, carboplatin and mitomycin-C
- medicines used to help fight infection, following chemotherapy e.g. filgrastim and pegfilgrastim
- some medicines used to treat infections e.g. itraconazole, fluconazole, voriconazole, isoniazid, ciprofloxacin, norfloxacin and ofloxacin
- some heart medications e.g. nifedipine or digoxin
- medicines to treat gout e.g. allopurinol, colchicine, probenecid or sulfinpyrazone
- phenytoin, a medicine to prevent seizures, fits or epilepsy
- vaccines
- St John's wort.

These medicines may be affected by DBL Vincristine Sulfate 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.

Vaccinations

Do not have any vaccinations (immunisations) without your doctor's approval while you are being treated with vincristine, and for up to 12 months after you stop treatment with it.

Vincristine may lower your body's resistance to infection and there is a chance that you may get the infection the immunisation is meant to prevent.

In addition, other people living in your household should not take oral polio vaccine (sabin) since there is a chance they could pass the polio virus on to you.

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 Vincristine Sulfate Injection.

4. How is DBL Vincristine Sulfate Injection 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 weight, age, blood tests, how well your liver is working, and whether or not other medicines are being given at the same time.

When DBL Vincristine Sulfate Injection is given

- Vincristine is usually given as a course of injections at weekly intervals.

How it is given

- DBL Vincristine Sulfate Injection is given as a slow injection (drip) into a vein. Vincristine must only be given by a doctor or nurse.
- Several courses of vincristine therapy may be needed, depending on your response to treatment.
- Additional treatment should not be repeated until your blood cell numbers return to acceptable levels and any unwanted effects have been controlled.

If you are given too much DBL Vincristine Sulfate Injection

As DBL Vincristine Sulfate 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 side effects after being given this medicine, tell your doctor or nurse immediately.

Symptoms of vincristine overdose include some of those listed in Section [6. Are there any side effects?](#), but are usually of a more severe nature.

Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor or pharmacist if you have any concerns.

5. What should I know while receiving DBL Vincristine Sulfate Injection?

Things you must do

- Tell your doctor, nurse or pharmacist if you have any concerns before, during or after administration of DBL Vincristine Sulfate Injection.
- Tell any other doctors, dentists, and pharmacists who are treating you that you are being given DBL Vincristine Sulfate Injection.

- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given DBL Vincristine Sulfate Injection.
- If you plan to be vaccinated within a year of being given DBL Vincristine Sulfate Injection, tell the doctor before you are vaccinated.
- If you or your partner become pregnant while being given or soon after being given DBL Vincristine Sulfate Injection, tell your doctor or pharmacist.

Reducing the risk of infection or bleeding

DBL Vincristine Sulfate Injection can temporarily lower the number of white blood cells in your blood, increasing the chance of you getting an infection. It can also lower the number of platelets, which are necessary for proper blood clotting. If this occurs, there are certain precautions you can take, especially when your blood count is low, to reduce the risk of infection or bleeding:

- If you can, 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 painful or difficult urination.
- 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.
- Do not touch your eyes or the inside of your nose unless you have just washed your hands and have not touched anything else in the meantime.
- Be careful not to cut yourself when you are using sharp objects such as a safety razor or fingernail or toenail cutters.
- Avoid contact sports or other situations where bruising or injury could occur.
- Be sure to keep all of your doctors' appointments so that your progress can be checked.

Protecting others from DBL Vincristine Sulfate Injection and its breakdown products

DBL Vincristine Sulfate Injection and its 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:

- Flush the toilet twice to dispose of any body fluids and waste.
- Wear 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.

Driving or using machines

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

DBL Vincristine Sulfate Injection may cause dizziness, tiredness or affect vision or movement in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Looking after your medicine

DBL Vincristine Sulfate Injection will be stored in the pharmacy or on the ward. It must be kept in a refrigerator, where the temperature stays between 2-8°C.

Getting rid of any unwanted medicine

Your doctor, nurse or pharmacist will dispose of any left-over medicine.

6. Are there any side effects?

Tell your doctor, pharmacist or nurse as soon as possible if you do not feel well while you are being given DBL Vincristine Sulfate Injection, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, vincristine may have unwanted 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 vincristine you receive.

The effects of DBL Vincristine Sulfate Injection may take some time to occur and therefore some side effects may be delayed. It is possible that the unwanted side effects may not occur until months after vincristine is given.

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
Skin-related: • hair loss • unusual perspiration • increase in sunburn • tingling or burning sensation. Gastrointestinal disorders: • diarrhoea, nausea or vomiting, loss of appetite and weight loss • inflamed gums.	Speak to your doctor if you have any of these side effects and they worry you.

Side effects	What to do
General disorders: - headache - impotence or reduced sexual drive.	
General disorders: - dizzy or light-headed when getting up from lying or sitting position - loss of feeling, hearing or taste. Gastrointestinal disorders: - constipation - mouth ulcers. Musculoskeletal disorders: - muscle wasting - muscle aches - jaw, bone, limb or back pain. Renal and urinary disorders: - increased frequency, difficulty or pain in passing urine, or incontinence. Nervous system disorders: - difficulty in walking. Eye disorders: - eye sight problems: blurred or double vision, temporary blindness. Psychiatric disorders: - trouble in sleeping, depression, nervousness, hallucinations, confusion and personality changes.	Tell your doctor or nurse as soon as possible if you notice any of the following
Injection site reactions: - Pain or redness at place of injection. Cardiac disorders: - tightness or pain in the chest, neck, back or arms as well as abnormal heartbeat. Allergies and respiratory disorders: - itchy rash, high temperature after the injection, swelling of the face, lips, tongue or throat and/or difficulty in breathing. Blood disorders: - signs of infection such as fever or chills, cough, hoarseness and sore throat - black, tarry stools; or blood in stools or urine; pinpoint red	Call your doctor or nurse straight away if you notice any of these side effects. These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

Side effects	What to do
spots on skin or any unusual bleeding or bruising. Gastrointestinal disorders: - abdominal or stomach cramps. Liver disorders: - abdominal pain or swelling, sudden weight gain - yellowing of the skin and eyes. Nervous system disorders: - loss of movement or coordination - muscle spasms - fits, seizures or convulsion.	

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.

Treatment with vincristine may cause changes in your blood cells which may be serious. Vincristine may also affect how your kidneys and liver work. Your doctor will arrange regular blood tests and checks to detect any changes.

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

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 or receiving any of your medicines.

7. Product details

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

What DBL Vincristine Sulfate Injection contains

Active ingredient (main ingredient)	Vincristine sulfate
Other ingredients (inactive ingredients)	Mannitol Water for injections Sodium hydroxide Sulfuric acid

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

DBL Vincristine Sulfate Injection does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What DBL Vincristine Sulfate Injection looks like

DBL Vincristine Sulfate Injection is a clear, colourless solution.

- DBL Vincristine Sulfate Injection 1 mg/1 mL vial (AUST R 16308).
- DBL Vincristine Sulfate Injection 2 mg/2 mL vial (AUST R 47249)

Who distributes DBL Vincristine Sulfate Injection

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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