

DBL™ Vincristine Sulfate Injection

Vincristine Sulfate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DBL Vincristine Sulfate Injection. This medicine is also called vincristine.

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 or pharmacist has weighed the risks of you being given DBL Vincristine Sulfate 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 with the medicine.

You may need to read it again.

What DBL Vincristine Sulfate Injection is used for

Vincristine belongs to a group of medicines known as antineoplastic or cytotoxic agents. You may also hear it referred to as chemotherapy.

Vincristine is classified as a vinca alkaloid. It interferes with the growth of cancer cells, which are eventually destroyed. Since the growth of normal body cells may also be affected by vincristine, other effects may also occur (see Side Effects).

Vincristine is used to treat certain cancers, including:

- 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.

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

Before you are given DBL Vincristine Sulfate Injection

When you must not be given it

You must not be given DBL Vincristine Sulfate Injection if you have an allergy to vincristine or any of the ingredients listed at the end of this leaflet.

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.

You must not be given vincristine if you have an allergy to any of the Vinca Alkaloids medicines eg. Vinblastine and Vindesine

You must not be given vincristine if you have the demyelinating form of Charcot-Marie-Tooth-Syndrome.

You must not be given DBL Vincristine Sulfate Injection if you are currently receiving radiotherapy to areas that include the liver.

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 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 Vincristine Sulfate injection and for one month after the last dose.

If you are not sure whether you should be given DBL Vincristine Sulfate 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
- any other substances, such as foods, preservatives or dyes

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

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

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 eg. Bleomycin, methotrexate, doxorubicin, asparaginase and mitomycin-C

- medicines used to help fight infection, following chemotherapy e.g. filgrastim and pegfilgrastim
- some medicines used to treat infections eg. itraconazole, fluconazole, voriconazole, isoniazid, ciprofloxacin, norfloxacin, ofloxacin
- some heart medications eg. nifedipine, digoxin
- medicines to treat gout e.g. allopurinol, colchicine, probenecid or sulfinpyrazone
- phenytoin, a medicine to prevent seizures/ fits/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.

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.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given vincristine.

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

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 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 (overdose)

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 severe side effects after being given this medicine, tell your doctor or nurse immediately.

In case of overdose, immediately contact the Poisons Information Centre for advice (telephone 13 11 26 in Australia). Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of vincristine overdose include some of those listed in the 'Side Effects' section 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.

While you are being given DBL Vincristine Sulfate Injection

Things you must do

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.

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.

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.

Things to be careful of

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. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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.

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:

- hair loss
- diarrhoea, nausea or vomiting, loss of appetite and weight loss
- headache
- unusual perspiration
- increase in sunburn
- tingling or burning sensation
- inflamed gums
- impotence or reduced sexual drive

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

- dizzy or light-headed when getting up from lying or sitting position
- constipation
- loss of feeling, hearing or taste
- difficulty in walking
- muscle wasting
- mouth ulcers
- different urination frequency
- jaw, bone, limb or back pain
- muscle aches
- partial loss of sight, blurred or double vision
- trouble in sleeping, depression, nervousness, hallucinations, confusion and personality changes

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

- tightness or pain in the chest, neck, back or arms as well as abnormal heartbeat
- wheezing or difficulty breathing, skin rash or swelling
- signs of infection such as fever or chills, cough, hoarseness and sore throat
- 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
- muscle spasms
- fits, seizures or convulsions

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

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.

Other side effects not listed above may 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.

After being given DBL Vincristine Sulfate Injection

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.

Storage

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.

After use, any unused portion of the injection will be discarded.

Product description

What it looks like

DBL Vincristine Sulfate Injection is a clear, colourless solution.

Ingredients

Active ingredient

- vincristine sulfate

Other ingredients

- mannitol
- water

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

Supplier

Pfizer Australia Pty Ltd
Sydney, NSW
Toll Free Number: 1800 675 229
www.pfizermedicalinformation.com.au

DBL Vincristine Sulfate Injection comes in the following sizes:

- 1 mg/1 mL vial AUST R 16308
- 2 mg/2 mL vial AUST R 47249

TM = Trademark

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