Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Vincristine Sulfate 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 benefits and risks. Your doctor has weighed the risks of you taking Vincristine Sulfate Injection against the benefits this medicine is expected to have for you.

This medicine is likely to be used while you are at the clinic or in hospital. If possible, please read this leaflet carefully before this medicine is given to you. In some cases this leaflet may be given to you after the medicine has been used.

If you have any concerns about taking this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet.

You may need to read it again.

What Vincristine Sulfate Injection is used for

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.

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.

Before you are given Vincristine Sulfate Injection

When you must not be given it

Do not use Vincristine Sulfate Injection if: you have an allergy to vincristine or any of the ingredients listed at the end of this

- leaflet
 you have an allergy to any of the Vinca Alkaloids medicines eg. Vinblastine and
- you suffer from Charcot-Marie-Tooth-Syndrome. This is a type of hereditary nerve disease.
- you are receiving or have received radiation therapy

If you are not sure whether any of these apply to you, check with your doctor.

You must not be given 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 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.

Before you are given it Tell your doctor if:

- 1. you have any allergies to:
- any other medicine
- any other substances, such as foods, preservatives or dyes
- 2. you are pregnant or intend to become pregnant
- 3. you are breastfeeding or plan to breastfeed
- you have or have had any medical conditions, especially the following:
- Gout
- · Kidney stones
- Any infections
- · Liver disease or jaundice
- Nerve or muscle disease.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any 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:

- Medicines to treat gout eg. Allopurinol, colchicine, probenecid or sulfinpyrazone
- Heart medicines eg. Nifedipine or digoxin
- Phenytoin, a medicine used to prevent seizures, fits or epilepsy
- Vaccines

- Medicines used to treat infections eg. Itraconazole, fluconazole, voriconazole, isoniazid, ciprofloxacin, norfloxacin and ofloxacin
- St John's wort
- Any other anti-cancer medicines eg. Bleomycin, methotrexate, doxorubicin, asparaginase and mitomycin-C.

In some cases, two different medicines may be used together by your doctor even if an interaction might occur. In these cases, your doctor may change your dose.

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 will advise you about continuing to take other medicines while you are receiving Vincristine Sulfate Injection.

How Vincristine Sulfate Injection is given

This medicine is given as a slow injection into a vein. Sometimes, it is diluted and given as a long injection. Vincristine Sulfate Injection must only be given by a doctor or nurse.

Your doctor will decide what dose, how often and how long you will receive it. 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.

Several courses of vincristine therapy may be needed, depending on your response to

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)

This rarely happens as Vincristine Sulfate Injection is administered under the care of a highly trained doctor.

However, if you are given too much vincristine, you may experience some of the effects listed under "Side Effects" below.

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

While you are being given Vincristine Sulfate Injection

Things you MUST do

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.
- If you become pregnant while under vincristine treatment, tell your doctor immediately.

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 Vincristine Sulfate Injection.

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given 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 Vincristine Sulfate Injection. If you plan to be vaccinated within a year of being given 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 Vincristine Sulfate Injection, tell your doctor or pharmacist.

Things you MUST NOT do

 Do not have any immunisations or vaccinations without your doctor's approval and for up to 12 months after you stopped treatment with it.

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 or nurse as soon as possible if you do not feel well while you are using vincristine.

Like other medicines, vincristine can cause some side effects. If they occur, most are likely to be minor or temporary. However, some may be serious and need medical attention

Ask your doctor, nurse or pharmacist to answer any questions that you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

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

Check with your doctor or nurse as soon as possible if any of the following side effects occur:

- dizzy or light-headed when getting up from lying or sitting position
- loss of feeling, hearing or taste
- eye sight problems: blurred or double vision, temporary blindness
- trouble in sleeping, depression, nervousness, hallucinations, confusion and personality changes
- increased frequency, difficulty or pain in passing urine, or incontinence
- · constipation or cramps
- hair loss
- · mouth ulcers
- muscle wasting, difficulty in walking
- · jaw, bone, limb or back pain
- muscle aches

Tell your doctor immediately if you notice any of the following:

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

· Pain or redness at place of injection

· Allergies

An allergy may appear as an itchy rash, high temperature after the injection, swelling of the face, lips, tongue or throat and/or difficulty in breathing.

Effects on the heart

Symptoms to look for are, tightness or pain in the chest, neck, back or arms as well as abnormal heartbeat.

Effects on nerves and muscles

Vincristine sometimes affects nerves in the hands and feet. This may appear as numbness, tingling, pain or weakness in the fingertips. Other symptoms are loss of movement, muscle control and reflexes, jaw pain, back pain, arm and leg pain, face pain, fits and coma.

· Bleeding disorders

Symptoms to look for are black, tarry stools; or blood in stools or urine; pinpoint red spots on skin and any unusual bleeding or bruising.

Infection

Symptoms to look for are fever, chills, cough, hoarseness and sore throat.

· Effects on the liver

Symptoms to look for are abdominal pain or swelling, sudden weight gain or yellowing of the skin and eyes

Other side effects not listed above may also occur in some patients. If you notice any other effects, check with your doctor. Some side effects may only be seen by your doctor.

Product description

What it looks like

Vincristine Sulfate Injection is a clear, colourless solution in a plastic vial.

AUST R 48055 Vincristine Sulfate Injection 2mg in 2mL (sterile) Plastic Vial

Ingredients

Vincristine Sulfate Injection contains Vincristine Sulfate, Mannitol and Water for Injections. It does not contain a preservative.

Supplier

Pfizer Australia Pty Ltd Sydney NSW

Toll Free Number: 1800 675 229 www.pfizermedicalinformation.com.au

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