Package leaflet: Information for the patient
Vincristine Sulfate 1 mg/ml solution for injection
vincristine sulfate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vincristine Sulfate solution for injection is and what it is used for

Vincristine sulfate is an anti-cancer medicine. Treatment with an anti-cancer medicine is sometimes called cancer chemotherapy.

Vincristine Sulfate solution for injection is used in the treatment of cancers of the blood (e.g. leukaemia or lymphomas), breast, head and neck or lung. It may be used to treat multiple myeloma (a cancer of plasma cells) and it may also be used in the treatment of some cancers in children. It may be used in a blood disorder known as idiopathic thrombocytopenic purpura (ITP) after other treatments have not been successful.

Vincristine Sulfate solution for injection may be given alone or in combination with other anti-cancer medicines.

2. What you need to know before you use Vincristine Sulfate solution for injection

Vincristine Sulfate solution for injection must never be injected intrathecally (into the spine).

Do not use Vincristine Sulfate solution for injection
- if you are allergic to vincristine sulfate or any of the other ingredients of this medicine (listed in section 6)
- if you have Charcot-Marie-Tooth syndrome (disease which causes weakness in the leg muscles)
- if you have an infection that is not being treated

Warnings and precautions

This medicine should only be given by healthcare professionals experienced in the use of vincristine or other similar medicines.

Talk to your doctor, pharmacist or nurse before using Vincristine Sulfate solution for injection

- **to make sure that this medicine is only given to you through a vein (it should not be given by any other route). If you notice any pain during, or soon after the injection is given, tell your doctor or nurse immediately**
- if you have a mental or nervous system disorder
- if you have liver trouble (can increase the severity of side effects that you may experience)
- if you have kidney cancer
- if you are having radiotherapy
- if you have breathing problems. Acute shortness of breath and severe bronchospasm have been reported following the administration of vinca alkaloids. Vincristine Sulfate is an example of a vinca alkaloid
- if you have a low white blood cell count measured on blood test
- if you have an infection

Special care is also needed if you are elderly.

Other medicines and Vincristine Sulfate solution for injection

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

There may be interactions between vincristine sulfate and other medicines such as:

- isoniazid (medicine used to treat tuberculosis)
- mitomycin-C (anti-cancer medicine)
- azole antifungals (a group of medicines used to treat fungal infections e.g. itraconazole, posaconazole, fluconazole, isavuconazole or voriconazole)
- ketoconazole (used to treat Cushing's syndrome, a disease characterised by an excess production of the hormone cortisol)
- L-asparaginase (used for treating some types of cancer)
- dactinomycin (used for treating some types of cancer)
- some anti-cancer drugs (e.g. containing platinum) that may cause problems with hearing or balance
- medicines which cause problems with passing water (urine). These should be stopped before you start treatment with vincristine sulfate
- medicines which cause problems with your nervous system e.g. walking difficulties, pins and needle or numbness
- vaccines known as "live" vaccines. Vincristine sulfate lowers the immune defences if used at the same time with this type of vaccine, it may cause severe infections. Check with your healthcare team how long you should wait prior to administration of live vaccines
- medicines for the treatment of low number of white blood cells (granulocyte-colony stimulating factors (G-CSFs)). Using G-CSFs at the same time with vincristine sulfate may decrease production of blood cells in the bone marrow (myelosuppression). Your healthcare team will ensure G-CSFs are started following the recommended period after vincristine treatment.

Phenytoin (medicine used to control fits) may not work as well when vincristine sulfate is used, so blood levels of phenytoin will need to be monitored.

Methotrexate used in the treatment of cancer may work better when used with vincristine sulfate.

St. John's wort used with vincristine sulfate should be given cautiously.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Women of childbearing potential should use appropriate contraception methods during treatment and for at least 7 months following the last dose of vincristine sulfate.

Men are advised to use appropriate contraception methods during treatment and for at least 4 months following the last dose of vincristine sulfate.

Because of the possibility of serious reactions to the nursing child, mothers are advised not to breast-feed during treatment and for 1 month following last dose of vincristine sulfate.

Treatment with vincristine sulfate can affect your fertility. Men and women who may want to have children after treatment with vincristine sulfate are recommended to discuss with their doctor options for fertility preservation.

Talk to your doctor about contraceptive methods that are right for you and your partner.

Driving and using machines
Do not drive or use machines if you experience any side effect which may lessen your ability to do so.

3. How to use Vincristine Sulfate solution for injection

This medicine must be given ONLY through a vein either by intravenous injection (IV) or infusion (IV) given by drip into a vein.

Vincristine sulfate is usually given once a week.

Vincristine sulfate is an irritant, if it accidentally gets into your eye tell your doctor or nurse immediately so that it may be washed out.

You may be given medicines to prevent constipation during treatment with vincristine sulfate.

Dosage
Your doctor will work out the correct dose of vincristine sulfate for you and how often it must be given.

The dose will depend on your medical condition, your size and how well your liver is working. Your doctor will tell how well your liver is working using a blood sample.

If you are given too much or too little Vincristine Sulfate solution for injection
This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too little or too much, however, tell your doctor or nurse if you have any concerns.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can have side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- severe allergic reaction – you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint.
- pain or swelling at the injection site during or immediately after the injection
- severe chest pains possibly radiating to the jaw or arm, sweating, breathlessness and nausea
- severe breathing problems or shortness of breath
- symptoms suggestive of sepsis – these may include a high fever or low temperature, shivering, fast heartbeat, rapid breathing, feeling faint, skin changes (cold, clammy and mottled or pale), altered mental state such as confusion or disorientation, decreased urination, nausea, vomiting etc. The presence of a few or several of these symptoms coupled with a rapid deterioration of general condition might indicate sepsis and immediate medical attention should be sought.

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

If any of the following happen, tell your doctor as soon as possible:

Very common side effects: may affect more than 1 in 10 people

- reduction in blood platelets, which increases risk of bleeding
- reduction in red blood cells which can make the skin pale and cause tiredness
- loss of appetite
- numbness or pins and needles
- constipation, stomach cramps
- being sick or feeling sick
- hair loss
- muscle weakness or muscle wasting
- pain in bones
- significant weight loss

Common side effects: may affect up to 1 in 10 people

- pain in jaw and throat
- diarrhoea
- problems with passing water (more or less urine than normal, or pain when passing urine)

Uncommon side effects: may affect up to 1 in 100 people

- coma

Not Known: frequency cannot be estimated from the available data

- infections
- fever, sore throat, skin rashes, or sores on your body and mouth ulcers (may indicate a drop in white blood cells)
- unexpected bruises
- elevated blood uric acid levels

- paralysis
- convulsions (fits)
- dizziness
- loss of reflexes
- headache
- disorders of brain function
- difficulty in walking
- difficulty with speech
- unusual eye movements
- worsening eyesight
- deafness or hearing loss
- build up of plaque in arteries
- raised or lowered blood pressure
- mild breathing problems
- tiredness
- liver problems
- back pain
- bladder problems
- soreness around the injection site after the injection

Vincristine sulfate may lead to changes in your blood cells, including a type of anaemia in which red blood cells are destroyed (haemolytic anaemia). Your doctor may take blood samples to monitor for these and also to check how well your liver is working.

There have been reports of other malignancies (cancers) occurring at a later date after vincristine sulfate has been used in combination with other anti-cancer drugs. This happens rarely.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vincristine Sulfate solution for injection

Keep this medicine out of the sight and reach of children.

Expiry
Do not use this medicine after the expiry date which is stated on the vial label and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage Conditions
Store in a refrigerator (2 ºC – 8 ºC). The vials should be kept in the outer carton, in order to protect from light.

Do not use this medicine if you notice evidence of precipitation or any other particulate matter.

Syringes, containers, absorbent materials, solution and any other contaminated material should be placed in a thick plastic bag or other impenetrable container and destroyed by burning. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Vincristine Sulfate solution for injection contains
The active substance is vincristine sulfate. Each millilitre (ml) of solution contains 1 milligram (mg) of vincristine sulfate. Each 2 ml vial contains 2 mg of vincristine sulfate.

The other ingredients are mannitol and water for injections.

What Vincristine Sulfate solution for injection looks like and contents of the pack
Vincristine Sulfate solution for injection is a colourless solution which comes in glass containers called vials.

It may be supplied in packs containing:
5 x 1 mg/1ml vials, 1 x 1 mg/1 ml syringe
5 x 2 mg/2 ml vials, 1 x 2 mg/2 ml syringe

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Hospira UK Limited
Walton Oaks
Walton-On-The-Hill
Dorking Road
Tadworth
Surrey
KT20 7NS
UK

Manufacturer
Pfizer Service Company BV
Hoge Wei 10
1930 Zaventem
Belgium

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Vincristine Sulfate 1 mg/ml solution for injection

The following information is intended for medical or healthcare professionals only

You should be experienced in the handling and use of cytotoxic agents and familiar with the Summary of Product Characteristics (SmPC) for this product. Reference should also be made to local policy guidelines on the safe handling of cytotoxic agents.

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities

Vincristine Sulfate solution for injection should not be mixed with any other drug and should not be diluted in solutions that raise or lower the pH outside the range 3.5 to 5.5. It should not be mixed with anything other than normal saline or 5% glucose solution.

Furosemide both in syringe and injected sequentially into Y-site with no flush between, results in immediate precipitation.

Shelf life

Unopened: 2 years
Once opened: use immediately.

Chemical and physical in-use stability has been demonstrated for up to 24 hours at 2 – 8 °C and at 25 °C when Vincristine Sulfate injection is diluted with 0.9% sodium chloride solution or 5% glucose solution in infusion bags and protected from light. If stored under normal light at 25 °C, when diluted with 0.9% sodium chloride solution or 5% glucose solution, the diluted product is stable for 8 hours or 4 hours respectively.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 – 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Instructions for use
This preparation is for intravenous use only. Fatal if given by any other route.

It should only be administered by individuals experienced in vincristine sulfate administration.

The calculated dose of vincristine sulphate solution should be administered ONLY through a vein either by intravenous injection or infusion (IV) according to the treatment protocol and under constant supervision for signs of extravasation.

Intravenous injection
Direct injection into the vein may be completed in about one minute.

Intravenous infusion
The diluted vincristine sulphate injection may be infused via a flexible plastic container (e.g.: infusion bag) either directly into an intravenous catheter/needle or into a running intravenous infusion. It is recommended to administer the solution over 5 to 10 minutes after dilution in a 50 ml infusion bag (50 ml sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution for injection). After administration the vein must be flushed through thoroughly. Care should be taken to avoid extravasation as this may cause local ulceration. If leakage into surrounding tissue should occur it may cause considerable irritation. The injection / infusion should be discontinued immediately and any remaining portion of the dose

should then be introduced into another vein. Local injection of hyaluronidase and the application of moderate heat to the area of leakage may help to disperse the drug and are thought to minimise discomfort and the possibility of cellulitis.

To reduce the potential for fatal medication errors due to incorrect route of administration, vincristine sulphate is recommended to be diluted in a flexible plastic container and prominently labelled as indicated FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES.

Cytotoxic Handling Guidelines

Administration: Should be administered only by or under the direct supervision of a qualified physician who is experienced in the use of cancer chemotherapeutic agents.

Preparation: Chemotherapeutic agents should be prepared for administration only by professionals who have been trained in the safe use of preparation.

Operations such as reconstitution of powder and transfer to syringes should be carried out only in the designated area. The work surface should be covered with disposable plastic-backed absorbent paper.

The personnel carrying out these procedures should be adequately protected with clothing, masks, gloves and eye shield.

Pregnant personnel are advised not to handle chemotherapeutic agents.

Use Luer-lock fittings on all syringes and sets. Large bore needles are recommended to minimise the pressure and the possible formation of aerosols. The latter may be reduced by the use of a venting needle.

Do not add extra fluid to the vial prior to removal of the dose. Withdraw the solution of vincristine sulfate into an accurate syringe, measuring the dose carefully. Do not add extra fluid to the vial in an attempt to empty it completely.

Adequate care and precaution should be taken in the disposal of items (syringes, needles, etc.) used to reconstitute cytotoxic drugs.

Whenever solution and container permit, parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

Contamination: Precautions should be taken to avoid the drug accidentally coming into contact with the eyes. If accidental contamination occurs, severe irritation (or if the drug was delivered under pressure, even corneal ulceration) may result. In the event of contact with the skin or eyes, the affected area should be washed with copious amounts of water or normal saline thoroughly and immediately. A bland cream may be used to treat the transient stinging of skin. Medical advice should be sought if the eyes are affected.

In the event of spillage, operators should put on gloves and mop the spilled material with a sponge kept in the area for that purpose. Rinse the area twice with water. Put all solutions and sponges into a plastic bag and then seal it.

Disposal: Syringes, containers, absorbent materials, solution and any other contaminated material should be placed in a thick plastic bag or other impervious container and incinerated.