Package leaflet: Information for the user

Vinblastine Sulfate 1 mg/ml Solution for Injection or Infusion
vinblastine 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 Vinblastine Sulfate is and what it is used for

Vinblastine Sulfate is a vinca alkaloid which is an anti-cancer medicine. Treatment with an anti-cancer medicine is sometimes called cancer chemotherapy.

Vinblastine Sulfate is sometimes used in the treatment of cancers of the lymph nodes, spleen, bone marrow, testicles, ovaries, skin and breast. It may be given alone or in combination with other anti-cancer medicines.

2. What you need to know before you use Vinblastine Sulfate

Vinblastine Sulfate must never be injected intramuscularly, subcutaneously or intrathecally (into the spine). Vinblastine Sulfate is for intravenous use only.

Do not use Vinblastine Sulfate
- if you are allergic to vinblastine sulfate or any of the other ingredients of this medicine (listed in section 6).
- if your blood tests show that you do not have enough white blood cells to fight infection (unless this is a result of your condition)
- if you have a bacterial infection which is not under control

Warnings and Precautions
Talk to your doctor, pharmacist or nurse before using vinblastine sulfate
- if you are an elderly patient in poor health or with skin sores
- if you have liver disease, including inflammation of the liver (hepatitis) or yellowing of your skin or the whites of your eyes (jaundice).

If you notice any of the following, and they do not go away, this might also mean that you have liver problems:

- Loss of appetite.
- Feeling itchy.
- Feeling tired, having no energy or feeling like you have flu.
- Feeling as though you are going to be sick or actually being sick.

Other medicines and Vinblastine Sulfate
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- The use of mitomycin with or without progesterone (anti-cancer medicines) with Vinblastine Sulfate may cause severe breathing problems especially if you have a pre-existing heart condition.
- The use of bleomycin or cisplatin (anti-cancer medicines) with Vinblastine Sulfate may cause heart and circulation problems, worsening of low white blood cell counts, decrease in kidney function, affect the nervous system, hearing problems, impaired balance and changes to sperm motility.
- The use of erythromycin (antibiotic) may increase the side effects of Vinblastine Sulfate such as low levels of white blood cells, muscle pain and constipation.
- Vinblastine Sulfate may reduce the effectiveness of medicines used to treat epilepsy, in particular, blood levels of phenytoin may need to be monitored more frequently.
- If furosemide injection is given at the same time as Vinblastine Sulfate, the two medicines may react with each other. Your doctor will take measures to ensure this does not happen.

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.

Contraception in women of childbearing potential
Women should always use highly effective birth-control (contraception) to prevent pregnancy during treatment and for at least 7 months after the last dose, as there is a risk of birth defects. Talk to your doctor about birth control methods that are right for you and your partner.

Contraception in men
Male patients with female partners of reproductive potential should always use highly effective contraception to prevent pregnancy during treatment and for at least 4 months after the last dose, as there is a risk of birth defects.

Breast-feeding
It is not known whether vinblastine sulfate is excreted in human milk. Because of the potential for serious side effects in nursing infants you must not breast-feed for the duration of vinblastine sulfate therapy and for at least one week after the last dose of treatment.

Fertility
Men and women have experienced reduced fertility while taking this medicine, but these effects are not likely to be permanent. You should talk to your doctor about your options to preserve fertility before starting the treatment with vinblastine sulfate.

Driving and using machines
This medicine does not generally affect the ability to drive or operate machinery. However, exercise caution if you experience any side effect which may lessen your ability to do so.

Vinblastine Sulfate contains sodium

This medicinal product contains 35.42 mg of sodium (main component of cooking/table salt) in each 10 ml vial. This is equivalent to 1.77% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Vinblastine Sulfate

This medicine will only be given into a vein. It is given by an infusion (drip) or an injection (using a syringe).

Vinblastine Sulfate is an irritant. If it accidentally gets into your eyes tell your doctor or nurse immediately so that it may be washed out.

You may be given medicines to prevent nausea and vomiting during treatment with Vinblastine Sulfate.

Dosage
Your doctor will work out the correct dose of Vinblastine 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.

Vinblastine Sulfate is usually given once a week.

If you are given too much or too little Vinblastine Sulfate
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 much or too little; however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

Like all medicines, this medicine can cause 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 administration site during or immediately after the administration
- feeling hot or cold – this may be a sign that you have an infection
- chest pain or shortness of breath

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

If any of the following happen, tell your doctor as soon as possible:
- convulsions (fits)
- blood in the stools/black tarry stools
- blistering of the skin, skin ulcers
- mouth ulcers
- sore throat
- significant weight loss/loss of appetite
- dizziness
- involuntary eye movements
- numbness or tingling in fingers and toes (“pins and needles”)

- mental depression
- stomach cramps, constipation or diarrhoea
- nausea or vomiting (feeling or being sick)
- pain in the chest, jaw, bones or where the tumour is
- headache
- weakness
- tiredness
- loss of tendon reflexes
- hair loss
- concentrated or decreased volume of urine
- a reduction in the production of semen and motility of semen
- ear pain or hearing loss
- shortness of breath, wheezing
- dry cough
- difficulty with balance
- increased blood pressure
- increase in amount and frequency of passing urine (due to changes in ADH levels)
- rectal bleeding
- reaction at injection site

Vinblastine Sulfate may lead to changes in your blood cells. Your doctor will take blood samples to monitor for these and also to check how well your liver is working. Based on your blood results and your general health, the doctor may decide to alter your treatment.

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:

Ireland
HPRA Pharmacovigilance. Website: www.hpra.ie.

Cyprus
Pharmaceutical Services
Ministry of Health
CY-1475 Nicosia
Tel.: +357 22608607
Fax: + 357 22608669
Website: www.moh.gov.cy/phs

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vinblastine Sulfate

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

Do not use this medicine after the expiry date which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

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

Store in a refrigerator (2 - 8°C). Keep the vial in the outer carton in order to protect from light.

For storage conditions after dilution of the medicinal product, see healthcare professional section of the leaflet.

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 protect the environment.

6. Contents of the pack and other information

What Vinblastine Sulfate contains
The active substance is vinblastine sulfate. Each millilitre (ml) of solution contains 1 milligram (mg) of vinblastine sulfate. Each vial contains 10 mg vinblastine sulfate.

The other ingredients are: sodium chloride, water for injections, sodium hydroxide and sulphuric acid (see section 2 '**Vinblastine Sulfate contains sodium**').

What Vinblastine Sulfate looks like and contents of the pack
Vinblastine Sulfate is a clear, colourless solution which comes in glass containers called vials. Each vial is wrapped in a clear, plastic protective sleeve.

It is supplied in packs containing 5 x 10 mg/10 ml vial.

Marketing Authorisation Holder

IE: Pfizer Healthcare Ireland Unlimited Company
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Vinblastine Sulfate 1 mg/ml Solution for Injection or Infusion

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 of the patient information leaflet, practical information on the preparation/handling of the medicinal product is provided here.

Incompatibilities
Vinblastine Sulfate is incompatible with furosemide. When injected sequentially into Y-site with no flush between or when mixed in a syringe, immediate precipitation results.

Administration

Vinblastine should not be given intramuscularly, subcutaneously or intrathecally.

FOR INTRAVENOUS USE ONLY. FATAL IF GIVEN BY OTHER ROUTES.

It is recommended to infuse Vinblastine Sulfate over 5 to 10 minutes after dilution in Sodium Chloride 0.9% to a final volume of 50 ml to 100 ml with a final concentration between 0.04 and 0.4 mg/ml. Alternatively, Vinblastine Sulfate may be injected directly into the vein over about one minute.

To minimize the possibility of extravascular spillage, it is suggested that the syringe and needle be rinsed with venous blood before withdrawal. The dose should not be diluted in large volumes of diluent (i.e., 100 to 250 ml) or given intravenously for prolonged periods (ranging from 30 to 60 minutes or more), since this frequently results in irritation of the vein and increases the chance of extravasation.

Because of the enhanced possibility of thrombosis, it is considered inadvisable to inject a solution of vinblastine sulfate into an extremity in which the circulation is impaired, or potentially impaired, by such conditions as compressing or invading neoplasm, phlebitis or varicosity.

As with other antineoplastic agents, vinblastine may cause a severe local reaction on extravasation. If leakage into the surrounding tissue should occur during intravenous administration of Vinblastine Sulfate, the administration should be discontinued immediately and any remaining portion of the dose should be introduced into another vein. Local injection of hyaluronidase with the application of heat has been used to disperse the drug in order to minimise discomfort and the possibility of tissue damage.

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

Pregnant personnel are advised not to handle chemotherapeutic agents.

For dilution of the medicinal product before administration:
Determine the dose of Vinblastine Sulfate to be administered (based upon the recommended dose and the patient's body surface area). Draw the appropriate volume of Vinblastine Sulfate up into a sterile syringe. Aseptic technique must be strictly observed since no preservative or bacteriostatic agent is present in Vinblastine Sulfate. The appropriate dose of Vinblastine Sulfate must be diluted in Sodium Chloride 0.9% to a final volume of 50 ml to 100 ml with a final concentration between 0.04 and 0.4 mg/ml.

Contamination: In the event of contact with the skin or eyes, the affected area should be washed with copious amounts of water or normal saline. 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 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.

Use immediately, discard any unused portions.

After dilution chemical and physical in-use stability has been demonstrated for:

Diluent	**Target Concentration**	**Storage Conditions**	**Time period**
0.9% (9 mg/ml) sodium chloride solution for infusion	0.04 mg/ml	2 - 8°C in the absence of light in non-PVC (polyolefin) infusion bags	19 days
0.9% (9 mg/ml) sodium chloride solution for infusion	0.4 mg/ml	2 - 8°C in the absence of light in non-PVC (polyolefin) infusion bags	35 days

From a microbiological point of view, the diluted 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 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.