

Package leaflet: Information for the patient

Vinblastine Sulfate 1 mg/ml solution for injection 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 solution for injection is and what it is used for
2. What you need to know before you use Vinblastine Sulfate solution for injection
3. How to use Vinblastine Sulfate solution for injection
4. Possible side effects
5. How to store Vinblastine Sulfate solution for injection
6. Contents of the pack and other information

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

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

Vinblastine Sulfate solution for injection is sometimes used in the treatment of cancers of the lymph nodes, spleen, bone marrow, testicles, placenta, kidney 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 solution for injection

Vinblastine Sulfate solution for injection must never be injected intrathecally (into the spine). Vincristine Sulfate solution for injection is for intravenous use only.

Do not use Vinblastine Sulfate solution for injection:

- if you are allergic to vinblastine or to any of the other ingredients of this medicine (listed in section 6)
- if you have a bacterial infection which is not under control
- 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 being treated)

Warnings and precautions

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

- 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

If in doubt, check with your doctor.

Other medicines and Vinblastine Sulfate solution for injection

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

Special care is needed if you are taking/using other medicines as some could interact with vinblastine sulfate, for example:

- the use of mitomycin-C with or without progesterone (anti-cancer medicines), with vinblastine 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 may cause heart and circulation problems (e.g. Raynaud's phenomenon), 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 such as low levels of white blood cells, muscle pain and constipation.
- vinblastine may reduce the effectiveness of medicines used to treat epilepsy (e.g. phenytoin)
- if you are having radiotherapy in the liver area your doctor will delay giving you vinblastine

The absence of menstruation (missing one or more menstrual periods) has occurred when Vinblastine Sulfate solution for injection has been used in combination with other drugs.

Pregnancy, breast-feeding and fertility

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding. Your doctor will decide if you should receive this medicine.

As there is a risk of birth defects, women of childbearing potential should use appropriate contraception methods during treatment with vinblastine sulfate.

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.

Driving and using machines

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

Vinblastine Sulfate solution for injection contains sodium and the vial stopper contains rubber

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

The vial stopper contains dry natural rubber (a derivative of latex), which may cause allergic reactions.

3. How to use Vinblastine Sulfate solution for injection

This medicine is given by injection (using a syringe) into a vein. Alternatively, it may be injected into the line of a running infusion (drip).

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. If your liver is not working properly the dose may be reduced.

Vinblastine sulfate is usually given once a week or less.

If you are given too much or too little Vinblastine 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 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 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

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

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

Not known: frequency cannot be estimated from the available data

- low blood cell count which may be present as anaemia, fever or infection, abnormal bleeding or bruising
- convulsions (fits)
- blood in the stools which may be accompanied by abdominal pain
- blistering of the skin, skin ulcers
- mouth ulcers
- sore throat
- significant weight loss
- dizziness
- numbness or pins and needles
- changes or loss of your tendon reflexes tested by tapping your tendon

- mental depression
- stomach cramps, pain in the abdomen, constipation or diarrhoea
- nausea or vomiting
- loss of appetite
- pain where the tumour is
- pain in your bones or muscles or jaw
- headache
- deafness or hearing difficulty which may be temporary or permanent hearing difficulty
- problems with your balance
- uncontrolled movements of the eyes, usually from side to side
- severe chest pain
- heart attack or stroke
- high blood pressure
- shortness of breath
- dry cough
- weakness
- tiredness and generally feeling unwell
- hair loss
- a reduction in the production of semen and motility of semen
- 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.

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

UK

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Vinblastine Sulfate solution for injection

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 vial label and carton after 'EXP'. The expiry date refers to the last day of that month.

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

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.

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

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 Vinblastine Sulfate solution for injection contains

The active substance is vinblastine sulfate. Each millilitre (ml) of solution contains 1 milligram (mg) of vinblastine sulfate.

The other ingredients are sodium chloride and water for injections (see section 2 **Vinblastine Sulfate solution for injection contains sodium and the vial stopper contains rubber**).

What Vinblastine Sulfate solution for injection looks like and contents of the pack

Vinblastine Sulfate solution for injection is a clear, colourless solution which comes in glass containers called vials.

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

Marketing Authorisation Holder and Manufacturer

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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.

The following information is intended for healthcare professionals only:

Cytotoxic Handling Guidelines

Administration: **Vinblastine sulfate is for intravenous use only.** 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.

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.

The vial stopper contains dry natural rubber (a derivative of latex), which may cause allergic reactions.