



TAJ PHARMA

PHARMACY MEDICINE
KEEP OUT OF REACH OF CHILDREN

VINCRIStINE SULPHATE

1 mg/ml Injection
5 mg/5 ml

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 or nurse.
- If you get any side effects, talk to your doctor. 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
2. What you need to know before you use Vincristine Sulfate solution for injection
3. How to use Vincristine Sulfate solution for injection
4. Possible side effects
5. How to store Vincristine Sulfate solution for injection
6. Contents of the pack and other information

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
- Premature babies or babies less than 4 weeks old must not receive Vincristine Sulfate solution for injection 5 mg/5 ml (see 'Vincristine Sulfate solution for injection contains benzyl alcohol and the vial stopper contains rubber' below).

Warnings and precautions

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

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- 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
- if you have kidney cancer
- if you are having radiotherapy
- if you have breathing problems
- if you have a low white blood cell count, measured on blood test
- if you have an infection

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

Special care is also needed if this medicine is given to the elderly or children between 4 weeks and 3 years old.

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.

Use of the following medicines may make the side effects of vincristine sulfate worse:

- isoniazid (medicine used to treat tuberculosis)
- mitomycin-C (anti-cancer medicine)
- itraconazole (a medicine used to treat fungal infections)
- L-asparaginase (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
- medicines which cause problems with your nervous system e.g. walking difficulties, pins and needle or numbness

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.

Pregnancy, breast-feeding and fertility

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic

acidosis").

Women of childbearing potential should use appropriate contraception methods during treatment with vincristine sulfate.

Driving and using machines

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

Vincristine Sulfate solution for injection contains benzyl alcohol and the vial stopper contains rubber

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Vincristine Sulfate solution for injection contains:

i. Benzyl alcohol

This medicine contains 9 mg benzyl alcohol in each 1 ml which is equivalent to 45 mg/5 ml.

Benzyl alcohol may cause allergic reactions. Benzyl alcohol may cause mild local irritation.

Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings syndrome") in young children.

Do not give to your new born baby (up to 4 weeks old), unless recommended by your doctor.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

ii. Latex

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

3. How to use Vincristine Sulfate solution for injection

This medicine is given by infusion (drip) into a vein.

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.

Vincristine sulfate is usually given once a week.

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.

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

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- 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. All of these serious side effects are rare.

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

- convulsions (fits)
- deafness or hearing loss
- worsening eyesight
- pain (may involve the side of the face, jaw, throat, neck, bones or muscles)
- dizziness
- fever, sore throat, skin rashes, or sores on your body and mouth ulcers (may indicate a drop in white blood cells)
- significant weight loss
- numbness or pins and needles
- difficulty in walking
- muscle weakness or muscle wasting
- difficulty with speech
- unusual eye movements
- problems with passing water (more or less urine than normal, or pain when passing urine)
- mild breathing problems
- raised or lowered blood pressure
- headache
- tiredness
- unexpected bruises
- stomach cramps, constipation or diarrhoea
- being sick or feeling sick
- hair loss
- soreness around the injection site after the injection
- infections with germs
- loss of appetite

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 has been used in combination with other anti-cancer drugs. This happens rarely.

Effects on fertility

Treatment with vincristine sulfate may permanently reduce fertility in men and women. Tell your doctor if you have concerns.

Reporting of side effects

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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 (see details below). 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



VINCRIStINE SULPHATE

1 mg/ml Injection
5 mg/5 ml

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