

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ABIC VINCRISTINE SULPHATE 1 mg/1 ml, vincristine sulphate

1 mg /1 ml, intravenous injection

ABIC VINCRISTINE SULPHATE 2 mg/2 ml, vincristine sulphate

1 mg /1 ml, intravenous injection

Read all of this leaflet carefully before you are given ABIC VINCRISTINE SULPHATE:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- ABIC VINCRISTINE SULPHATE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ABIC VINCRISTINE SULPHATE CONTAINS:

The active substance is vincristine sulphate 1 mg /1 ml.

The other ingredients are mannitol and water for injection.

2. WHAT ABIC VINCRISTINE SULPHATE IS USED FOR:

ABIC VINCRISTINE SULPHATE belongs to the group of medicines called vinca alkaloids. It is an anti-cancer medicine. Treatment with anti-cancer medicine is sometimes called cancer chemotherapy.

ABIC VINCRISTINE SULPHATE works by slowing or stopping the growth of cancer cells. It is used alone or in combination with other anti-cancer medicines.

ABIC VINCRISTINE SULPHATE is used for the treatment of the following types of cancer:

- Acute leukaemia (cancer of the blood, especially the type affecting the white blood cells) in adults and children
- Hodgkin's disease and related lymphomas.

Beneficial responses have been reported in patients with a variety of other neoplasms, particularly the following:

- Wilm's tumour
- Neuroblastoma
- Brain tumours
- Rhabdomyosarcoma
- Carcinoma of the breast
- Bladder
- Male and female reproductive systems.

ABIC VINCRISTINE SULPHATE may be given alone or in combination with other anticancer medicines.

3. BEFORE ABIC VINCRISTINE SULPHATE IS ADMINISTERED TO YOU:

ABIC VINCRISTINE SULPHATE must never be injected intrathecally (into the spine). This can cause death.

You should not be administered ABIC VINCRISTINE SULPHATE:

- if you are hypersensitive (allergic) to vincristine sulphate or any of the other ingredients of ABIC VINCRISTINE SULPHATE
- if you have a bacterial infection
- if you have a neuromuscular disorder, such as the demyelinating form of Charcot-Marie-tooth syndrome (disease which causes weakness in the leg muscles)
- if you have a liver function disorder
- if you have severe constipation and / or an impending obstruction in your intestine (especially in children)
- if you are treated with radiotherapy in which the liver is involved.

Tell your doctor or healthcare professional before being given the injection:

Special care should be taken with ABIC VINCRISTINE SULPHATE:

- ABIC VINCRISTINE SULPHATE should only be used under strict supervision by healthcare professionals who have experience in cancer treatment.
- that ABIC VINCRISTINE SULPHATE 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 healthcare professional immediately.
- if the drip leaks into surrounding tissues, tell your doctor or healthcare professional immediately.
- if you have previously been treated with other cancer medicines
- if you have a nervous system or neuromuscular disorder
- if you are elderly (you may be more susceptible to neurotoxicity)
- if you have a mental disorder
- if you have liver problems
- if you have heart problems (ischaemic cardiac disease)
- if you have a low white blood cell count measured by blood tests
- if you have kidney problems (increased serum uric acid)
- if you have an infection
- if you want to become pregnant

Care should be taken to avoid contact of ABIC VINCRISTINE SULPHATE with the eyes and skin.

Pregnancy and Breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before being administered ABIC VINCRISTINE SULPHATE.

You must not receive ABIC VINCRISTINE SULPHATE if you are pregnant or breastfeeding your baby.

If you become pregnant during the period in which you are being treated with ABIC VINCRISTINE SULPHATE, it can harm your unborn baby.

Male and female patients being treated with ABIC VINCRISTINE SULPHATE must take contraceptive

measures for the duration of treatment as well as 3 months after treatment has stopped.

ABIC VINCRISTINE SULPHATE can have genotoxic effects (can harm your DNA and cause mutations). Genetic counselling is thus recommended for patients wishing to have children after therapy.

Driving and using machinery:

ABIC VINCRISTINE SULPHATE may cause side effects affecting your nervous system, which can have an effect on your ability to drive or use machines. Do not drive or operate any machinery until you know how you are affected by ABIC VINCRISTINE SULPHATE.

Important information about some of the ingredients of ABIC VINCRISTINE SULPHATE:

ABIC VINCRISTINE SULPHATE contains mannitol and may have a laxative effect.

Using other medicines with ABIC VINCRISTINE SULPHATE:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

The use of the following medicines may make the side effects of ABIC VINCRISTINE SULPHATE worse:

- itraconazole, ketoconazole (medicines used to treat fungal infections)
- ritonavir, nelfinavir (medicines to treat HIV)
- erythromycin (antibiotic treating infections)
- nifedipine (for treating high blood pressure)
- nefazodone (an anti-depressant)
- other myelosuppressive cancer medicines, such as doxorubicin (especially with prednisone)
- dactinomycin, in patients with Wilms' tumour, severe liver toxicity is reported when ABIC VINCRISTINE SULPHATE is given concomitantly
- L-asparaginase, used for treating some types of cancer
- isoniazid, a medicine used to treat tuberculosis (TB)
- ciclosporin and tacrolimus

- mitomycin-C (anti-cancer medicine)
- radiation therapy
- dactinomycin (used for treating some types of cancer)
- some anti-cancer drugs (eg containing platinum) that may cause problems with hearing or balance

ABIC VINCRISTINE SULPHATE may decrease the effectivity of the following medicines:

- phenytoin (medicines used to control fits), your blood levels of phenytoin will need to be monitored
- digoxin (a heart medication), a dosage adjustment of digoxin may be necessary

Methotrexate used in the treatment of cancer may work better when used with ABIC VINCRISTINE SULPHATE.

You should not receive any vaccines (live or killed virus) for 3 months, to 1 year after treatment.

Your antibody response to the vaccine may be decreased. If you need to receive a vaccine, please consult your doctor managing your cancer treatment first.

4. HOW TO RECEIVE ABIC VINCRISTINE SULPHATE:

Do not share medicines prescribed for you with any other person.

Your doctor will tell you how long your treatment with ABIC VINCRISTINE SULPHATE will last. Do not stop treatment early. If you have the impression that the effect of ABIC VINCRISTINE SULPHATE is too strong or too weak, tell your doctor or pharmacist.

You will not be expected to give yourself ABIC VINCRISTINE SULPHATE. It will be given to you by a person who is qualified to do so.

Your medicine will be given to you directly into a vein or into the tubing of running intravenous infusion. ABIC VINCRISTINE SULPHATE injection may be completed in about one minute.

Your doctor will work out the correct dose of ABIC VINCRISTINE SULPHATE for you and how often it must be given.

The usual dose of ABIC VINCRISTINE SULPHATE for adults is 1,4 mg/m² or 25 – 75 µg/kg weekly.

For other malignancies 25 µg/kg may be given weekly and reduced to 5 – 10 µg/kg for maintenance.
For children the dosage is 2 mg/m² body-surface or 50 µg/kg body mass increasing by weekly increments of 25 µg/kg to a maximum of 150 µg/kg.

Your doctor will do blood tests to determine your white-cell counts before and after giving each dose.

If you receive more ABIC VINCRISTINE SULPHATE than you should:

Since a healthcare professional will administer ABIC VINCRISTINE SULPHATE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of ABIC VINCRISTINE SULPHATE:

Do not receive a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

ABIC VINCRISTINE SULPHATE can have side effects.

Not all side effects reported for ABIC VINCRISTINE SULPHATE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ABIC VINCRISTINE SULPHATE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop receiving ABIC VINCRISTINE SULPHATE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- yellowing of the skin, nails and eyes, also called jaundice, right upper quadrant pain.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ABIC VINCRISTINE SULPHATE. You may need urgent medical attention or

hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- 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.
- severe chest pains possibly radiating to the jaw or arm, sweating, breathlessness and nausea
- severe breathing problems or shortness of breath
- pain or swelling at the injection site during or immediately after the injection

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- blood disorders such as reduction in the number of white cells in the blood, red cell or haemoglobin deficiency in the blood, destroying and removal of red blood cells from the bloodstream, low blood platelet count, bleeding
- constipation, stomach cramps
- pain in the salivary gland below the ear
- nausea
- vomiting
- problems with passing water (more or less urine than normal, or pain when passing urine)
- throat pain
- numbness (pins and needles)
- difficulty in walking
- lack of muscle control (voluntary control)
- muscle weakness or muscle wasting

- difficulty with speech
- hoarseness due to muscle weakness of the larynx
- bilateral vocal cord paralysis which can be life-threatening
- convulsions (fits)
- hair loss (reversible)
- pain (may involve the jaw, neck, bones, limbs or muscles)

Less frequent side effects:

- low sodium, electrolyte levels in the blood (body retains water)
- dehydration
- reduced appetite
- unusual eye movements
- hearing loss (temporary or permanent)
- dizziness, loss of balance
- heart problems (patients previously treated with mediastinal radiation)
- raised or lowered blood pressure
- inflamed and sore mouth, mouth ulcers, inflamed oesophagus
- stomach pain, stomach bleeding, diarrhoea
- paralysis of the intestinal muscles
- gut problems (ulceration, dead gut)
- infertility, missed period, enlargement of breasts in men
- depression, nervousness, sleeplessness, confusion and seeing and hearing things that don't exist
- impaired thought and emotions that contact is lost with external reality.
- headache
- fever
- inflammation of the veins
- skin infection with germs
- significant weight loss

Side effects with unknown frequency:

- infection (fever, sore throat, skin rashes, or sores on your body and mouth ulcers)
- double vision, total or partial loss of vision
- muscle wasting

There have been reports of other malignancies (cancers) occurring at a later stage after ABIC VINCRISTINE SULPHATE has been used in combination with other anti-cancer drugs.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF ABIC VINCRISTINE SULPHATE:

Store in refrigerator, between 2 °C and 8 °C.

Keep in outer carton to protect from light.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

After dilution:

Chemical and physical in-use stability of the solution prepared for injection or infusion has been demonstrated for 48 hours at 2 to 8 °C or 24 hours at 15 to 25 °C when diluted to a concentration range of 0,01 mg/ml to 0,1 mg/ml in 9 mg/ml (0,9 %) sodium chloride solution for infusion or in 50 mg/ml (5 %) glucose solution for infusion.

From a microbiological point of view, the diluted solution 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.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF ABIC VINCRISTINE SULPHATE:

Single dose, colourless glass vials containing 1 ml and 2 ml solution for injection.

8. IDENTIFICATION OF ABIC VINCRISTINE SULPHATE:

Clear, colourless to yellowish solution.

9. REGISTRATION NUMBER:

ABIC VINCRISTINE SULPHATE 1 mg/1 ml: T/26/221

ABIC VINCRISTINE SULPHATE 2 mg/2 ml: W/26/241

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Teva Pharmaceuticals (Pty) Ltd

Maxwell Office Park

Magwa Crescent West

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11. DATE OF PUBLICATION:

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