TAJ PHARMA HARMACY MEDICINE KEEP OUT OF REACH OF CHILDREN



### Vratucan® Vincristine Is Used For: Cancers acute leukemia, Hodgkin's and non- Hodgkin's lymphoma, neuroblastoma, rhabdomyosarcoma, Ewing's sarcoma.

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

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 iniection

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 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

## 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 prob lems

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 Page 2 of 7

• 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)

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

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

# 5. How to store Vincristine Sulfate solution for injection

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

This medicine must not be used 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°C - 8 °C). Keep vial 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.

# 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 5 ml vial contains 5 mg of vincristine sulfate.

The other ingredients are mannitol, benzyl alcohol and water for injection

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 Page 3 of 7

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 gasping 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

feel you are going to faint.

in immediate precipitation.

Instructions for use

immediately after the injection

immediately:

Page 4 of 7

Like all medicines, this medicine can have side effects, although not everybody gets them. If any of the following happen, tell your doctor

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

pain or swelling at the injection site during or

severe chest pains possibly radiating to the jaw or

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

This preparation is for intravenous use only. Fatal if given by any other route. It should only be administered by individuals experienced in vincristine administration.

It is recommended to infuse vincristine sulfate over 5

to 10minutes after dilution in a 50 ml infusion bag with

Sodium Chloride 9 mg/ml (0.9%) Solution for

Injection. After administration the vein must be

Care should be taken to avoid extravasation. If

leakage into surrounding tissue should occur it may cause considerable irritation. The injection 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

Administration: Should be administered only by or

under the direct supervision of a qualified physician

who is experienced in the use of cancer

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

minimise discomfort and the possibility of cellulitis.

Cytotoxic Handling Guidelines

chemotherapeutic agents.

- 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

Page 5 of 7

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.

Sulfate solution for injection contains benzyl and the

vial stopper contains rubber).

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 5 mg/5 ml

Marketing authorisation holder and manufacturer

Manufactured in India by TAJ PHARMACEUTIĆALS LTD. Mumbai, India at SURVEY NO.188/1 TO 189/1,190/1 TO 4 ATHIYAWAD, DABHEL, DAMAN- 396210 (INDIA)

This leaflet was last revised in May 2019

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

Vincrisitine Sulfate solution for injection should not be

#### designated

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

## Page 7 of 7

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.

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





