Vincristine Sulphate

Vincristine Sulphate

1 mg/ml Solution for injection

Reference Market: UK

AfME Markets using same as LPD: Saudi Arabia

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Vincristine Sulphate 1 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains 1 mg of vincristine sulphate
Each 2 ml contains 2 mg of vincristine sulphate

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

A sterile, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vincristine Sulphate is used either alone or in conjunction with other oncolytic drugs for the treatment of:

1. Leukaemias, including acute lymphocytic leukaemia, chronic lymphocytic leukaemia, acute myelogenous leukaemia and blastic crisis of chronic myelogenous leukaemia.

2. Malignant lymphomas, including Hodgkin's disease and non-Hodgkin's lymphomas.

3. Multiple myeloma.

4. Solid tumours, including breast carcinoma, small cell bronchogenic carcinoma, head and neck carcinoma and soft tissue sarcomas.

5. Paediatric solid tumours, including Ewing's sarcoma, embryonal rhabdomyosarcoma, neuroblastoma, Wilms' tumour, retinoblastoma and medulloblastoma.

6. Idiopathic thrombocytopenic purpura. Patients with true ITP refractory to splenectomy and short-term treatment with adrenocortical steroids may respond to vincristine but the medicinal product is not recommended as primary treatment of this disorder. Recommended weekly doses of vincristine given for 3 to 4 weeks have produced permanent remissions in some patients. If patients fail to respond after 3 to 6 doses, it is unlikely that there will be any beneficial results with additional doses.

4.2 Posology and method of administration

Posology

The following dosage regimens have been used:

Adults: The drug is administered intravenously at weekly intervals. The recommended dose is 1.4 to 1.5 mg/m^2 up to a maximum weekly dose of 2 mg.

Children: The suggested dose is 1.4 to 2 mg/m^2 given on a weekly basis with a maximum weekly dose of 2 mg. For children weighing 10 kg or less the starting dose should be 0.05 mg/kg administered as a weekly intravenous injection.

Elderly: The normal adult dose is still appropriate in the elderly.

Hepatic Impairment: Because of the hepatic metabolism and biliary excretion of vincristine, reduced doses are recommended in patients with obstructive jaundice or other hepatic impairment. Patients with liver disease sufficient to decrease biliary excretion may experience an increase in the severity of side-effects. A 50 per cent reduction in the dose of vincristine sulphate is recommended for patients having a direct serum bilirubin value above 3 mg/100 ml (51 micromol/l).

Caution: If leakage into surrounding tissue should occur during intravenous administration of vincristine, 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 the hyaluronidase and the application of moderate heat to the area of leakage help to disperse the drug and are thought to minimise discomfort and the possibility of cellulitis.

Method of administration

Precautions to be taken before handling or administering the medicinal product.

This preparation is for intravenous (IV) use only. It should only be administered by individuals experienced in vincristine administration.

FOR INTRAVENOUS USE ONLY

FATAL IF GIVEN BY ANY OTHER ROUTE

Can be fatal if administered intrathecally (see sections 4.3 and 4.4). See section 4.4 for use for the treatment of patients accidentally given intrathecal vincristine sulphate.

Vincristine sulphate is administered by intravenous infusion at weekly intervals.

Great care should be exercised in calculating and administering the dose, as overdosage may be extremely serious or even fatal. The calculated dose of the vincristine solution should be administered ONLY through a vein either by intravenous injection or infusion (IV) according to the treatment protocol and under constant supervision for signs of extravasation. The dose should not be increased beyond the level which produces therapeutic benefit. Individual doses should not exceed 2 mg; and white cell counts should be carried out before and after giving each dose.

Intravenous injection
Direct injection into the vein may be completed in about one minute.

Intravenous infusion
The diluted vincristine sulphate injection may be infused via a flexible plastic container (e.g.: infusion bag) either directly into an intravenous catheter/needle or into a running intravenous infusion (see section 6.2). It is recommended to administer the solution over 5 to 10 minutes after dilution in a 50 ml infusion bag (50 ml sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution for injection). After administration the vein must be flushed through thoroughly. Care should be taken to avoid extravasation as this may cause local ulceration.

With the vial presentations, do not add extra fluid to the vial prior to removal of the dose. Withdraw the solution of Vincristine Sulphate into an accurate dry syringe, measuring the dose carefully. Do not add extra fluid to the vial in an attempt to empty it completely.

TO REDUCE THE POTENTIAL FOR FATAL MEDICATION ERRORS DUE TO INCORRECT ROUTE OF ADMINISTRATION, VINCRISTINE SULPHATE INJECTION IS RECOMMENDED TO BE DILUTED IN A FLEXIBLE PLASTIC CONTAINER AND PROMINENTLY LABELLED AS INDICATED **FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES** (see sections 4.3 and 4.4).

Because of the narrow range between therapeutic and toxic levels and variations in response, the dosage must always be adjusted to the individual.

For instructions on dilution of the medicinal product before administration, see section 6.6**.**

4.3 Contraindications

Intrathecal administration of vincristine sulphate is usually fatal.

Hypersensitivity to vincristine sulphate or to any of the excipients listed in section 6.1.

Patients with the demyelinating form of Charcot-Marie-Tooth syndrome should not be given vincristine.

Careful notice should also be given to those conditions listed in section 4.4 .

4.4 Special warnings and precautions for use

This preparation is for intravenous use only (see sections 4.2 and 4.3). It should be administered by physicians experienced in the administration of vincristine sulphate. Vincristine Sulphate should not be given by intrathecal, intramuscular or subcutaneous injection. The intrathecal administration of vincristine sulphate usually results in death.

Syringes containing this product should be labelled 'VINCRISTINE FOR INTRAVENOUS USE ONLY. FATAL IF GIVEN BY OTHER ROUTES'.

Emergency Treatment of accidental intrathecal administration:
After inadvertent intrathecal administration, immediate neurosurgical intervention is required in order to prevent ascending paralysis leading to death. In a very small number of patients, life-threatening paralysis and subsequent death was averted but resulted in devastating neurological sequelae, with limited recovery afterwards.

Based on the published management of these survival cases, if vincristine is mistakenly given by the intrathecal route, the following treatment should be initiated **immediately after the injection:**

1. Removal of as much CSF as is safely possible through the lumbar access.

2. Insertion of an epidural catheter into the subarachnoid space via the intervertebral space above initial lumbar access and CSF irrigation with lactated Ringer's solution. Fresh frozen plasma should be requested and, when available, 25 ml should be added to every 1 litre of lactated Ringer's solution.

3. Insertion of an intraventricular drain or catheter by a neurosurgeon and continuation of CSF irrigation with fluid removal through the lumbar access connected to a closed

drainage system. Lactated Ringer's solution should be given by continuous infusion at 150 ml/h, or at a rate of 75 ml/h when fresh frozen plasma has been added as above.

The rate of infusion should be adjusted to maintain a spinal fluid protein level of 150 mg/dl.

The following measures have also been used in addition but may not be essential:

Folinic acid has been administered intravenously as a 100 mg bolus and then infused at a rate of 25 mg/h for 24 hours, then bolus doses of 25 mg 6-hourly for 1 week. Intravenous administration of glutamic acid 10 g over 24 hours, followed by 500 mg three times daily by mouth for one month. Pyridoxine has been given at a dose of 50 mg 8 hourly by intravenous infusion over 30 minutes. Their roles in the reduction of neurotoxicity are unclear.

Vincristine Sulphate is a vesicant and may cause severe local reaction or extravasation, see *Caution* in section 4.2.

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

Leucopenia is less likely following therapy with vincristine sulphate than is the case with other oncolytic agents. It is usually neuromuscular rather than bone marrow toxicity that limits dosage. However, because of the possibility of leucopenia, both physician and patient should remain alert for signs of any complicating infection. If leucopenia or a complicating infection is present, then administration of the next dose of vincristine sulphate warrants careful consideration. On occasions, these infections may prove fatal.

Acute uric acid nephropathy, which may occur after administration of oncolytic agents, has also been reported with vincristine sulphate.

As vincristine sulphate penetrates the blood-brain barrier poorly, additional agents and routes of administration may be required for central nervous system leukaemias.

The neurotoxic effect of vincristine sulphate may be additive with other neurotoxic agents or increased by spinal cord irradiation and neurological disease. Elderly patients may be more susceptible to the neurotoxic effects of vincristine sulphate.

Both in vivo and in vitro laboratory tests have failed to demonstrate conclusively that this product is mutagenic. Fertility following treatment with vincristine alone for malignant disease has not been studied in humans. Clinical reports of both male and female patients who received multiple-agent chemotherapy that included vincristine indicate that azoospermia and amenorrhoea can occur in post pubertal patients. Recovery occurred many months after completion of chemotherapy in some but not all patients. When the same treatment is administered to prepubertal patients, it is much less likely to cause permanent azoospermia and amenorrhoea.

Patients who received vincristine chemotherapy in combination with anticancer drugs known to be carcinogenic have developed second malignancies. The contributing role of vincristine in this development has not been determined. No evidence of carcinogenicity was found following intraperitoneal administration in rats and mice, although this study was limited.

Care should be exercised to avoid accidental contamination of the eyes as vincristine sulphate is highly irritant and can cause corneal ulceration. The eye should be washed immediately and thoroughly.

Vincristine can cause foetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving vincristine (see sections 4.6 and 5.3).

4.5 Interaction with other medicinal products and other forms of interaction

The neurotoxicity of vincristine sulphate may be additive with that of isoniazid and other drugs acting on the nervous system.

Acute shortness of breath and severe bronchospasm have been reported following the administration of vinca alkaloids. These reactions have been encountered most frequently when the vinca alkaloid was used in combination with mitomycin-C and may be serious when there is pre-existing pulmonary dysfunction. The onset may be within minutes or several hours after the vinca is administered and may occur up to 2 weeks following the dose of mitomycin. Progressive dyspnoea, requiring chronic therapy, may occur. Vincristine should not be re-administered.

The simultaneous oral or intravenous administration of phenytoin and antineoplastic chemotherapy combinations, that included vincristine sulphate, have been reported to reduce blood levels of the anticonvulsant and to increase seizure activity. Although the contribution of the vinca alkaloids has not been established, dosage adjustment of phenytoin, based on serial blood level monitoring, may need to be made when it is used in combination with vincristine.

Caution should be exercised in patients concurrently taking drugs known to inhibit/induce drug metabolism by hepatic cytochrome P450 isoenzymes in the CYP 3A subfamily, or in patients with hepatic dysfunction. Concurrent administration of vincristine sulphate with itraconazole or fluconazole (known inhibitor of the metabolic pathway) have been reported to cause an earlier onset and/or an increased severity of neuromuscular side-effects (see section 4.8), inducers like St. John's wort should be given cautiously. This interaction is presumed to be related to inhibition of the metabolism of vincristine.

When vincristine sulphate is used in combination with L-asparaginase, it should be given 12 to 24 hours before administration of the enzyme in order to minimise toxicity, since administering L-asparaginase first may reduce hepatic clearance of vincristine.

When chemotherapy is being given in conjunction with radiation therapy through portals which include the liver, the use of vincristine should be delayed until radiation therapy has been completed.

Vincristine Sulphate appears to increase the cellular uptake of methotrexate by malignant cells and this principle has been applied in high-dose methotrexate therapy.

Severe hepatotoxicity, including veno-occlusive disease has been reported in patients treated with a combination of vincristine and dactinomycin for renal carcinoma.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/Contraception in males and females
Women of childbearing potential should be advised to avoid becoming pregnant while receiving vincristine sulphate. Due to the potential for genotoxicity, teratogenicity, and embryo toxicity, female patients of reproductive potential are advised to use highly effective contraception during treatment and for at least 7 months following last dose of vincristine sulphate.

Due to the potential for genotoxicity, male patients with female partners of reproductive potential are advised to use highly effective contraception during treatment and for at least 4 months following the last dose of vincristine sulphate.

Pregnancy
Caution is necessary with the use of all oncolytic drugs during pregnancy. Both men and women receiving vincristine should be informed of the potential risk of adverse effects. Reliable methods of contraception or abstinence are recommended.

Vincristine can cause foetal harm following maternal or paternal exposure, although there are no adequate and well-controlled studies (see section 5.3).

If vincristine is used during pregnancy or if the patient becomes pregnant while receiving this medicinal product she should be informed of the potential hazard to the foetus.

There are no or limited amount of data from the use of vincristine sulphate in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3.)

Breast-feeding
There is insufficient information on the excretion of vincristine sulphate in human breast milk. Because of the potential for serious adverse reactions due to vincristine sulphate in nursing infants, the mother should be advised not to breast-feed while on vincristine sulphate therapy and for 1 month following last dose of treatment or to discontinue/abstain from vincristine sulphate therapy, taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility
Based on clinical reports, male and female fertility may be compromised (see section 4.4). It is recommended to discuss fertility preservation with men and women prior to treatment.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

In general, adverse reactions are reversible and are related to dosage size and cumulative dosage. The use of small amounts of vincristine daily for long periods is not advised. The most common adverse reaction is alopecia; the most troublesome adverse reactions are neuromuscular in origin.

When single weekly doses of vincristine are employed, the adverse reactions of leukopenia, neuritic pain, and constipation are usually of short duration (i.e. less than 7 days). When the dosage is reduced, these reactions may lessen or disappear. They seem to be increased when the calculated amount of medicinal product is given in divided doses. Other adverse reactions, such as alopecia, sensory loss, paraesthesia, difficulty in walking, slapping gait, loss of deep-tendon reflexes and muscle wasting may persist for at least as long as therapy is continued. Generalised sensorimotor dysfunction may become progressively more severe with continued treatment, but the neuromuscular difficulties may persist for prolonged periods in some patients. Re-growth of hair may occur while maintenance therapy continues.

The following adverse reactions have been reported:

Infections and infestations: Infection, sepsis, neutropenic sepsis

Neoplasms benign, malignant and unspecified (incl cysts and polyps): The occurrence of secondary malignancies has been reported rarely in patients treated with vincristine in association with other anticancer drugs known to be carcinogenic.

Blood and lymphatic system disorders: Leukopenia and neutropenia; vincristine does not appear to have any constant or significant effect upon the platelets or the red blood cells, however, anaemia, haemolytic anaemia and thrombocytopenia have been reported. If thrombocytopenia is present when treatment with vincristine sulphate is begun, it may actually improve before the appearance of marrow remission. Clinical consequences of leukopenia may be fever, infections and sepsis. There have been occasional reports of fatal infections during vincristine therapy.

Immune system disorders: Rare cases of allergic-type reactions, such as anaphylaxis, rash and oedema, temporally related to vincristine therapy have been reported in patients receiving vincristine as a part of multi-drug chemotherapy regimens.

Endocrine disorders: Rare occurrences of a syndrome attributable to inappropriate anti-diuretic hormone secretion have been observed in patients treated with vincristine. There is a high urinary sodium excretion in the presence of hyponatraemia; renal or adrenal disease, hypotension, dehydration, azotaemia and clinical oedema are absent. With fluid deprivation, improvement occurs in the hyponatraemia and in the renal loss of sodium.

Metabolism and nutrition disorders: Anorexia.

Nervous system disorders (often dose limiting): Neuritic pain, sensory loss, paraesthesia, difficulty in walking, loss of deep tendon reflexes, ataxia, paresis, foot drop and cranial nerve palsies, especially ocular palsies and laryngeal nerve paralysis. Frequently, there appears to be a sequence in the development of neuromuscular side effects. Initially, one may encounter only sensory impairment and paraesthesia. With continued treatment, neuritic pain may appear and later, motor difficulties. No reports have yet been made of any agent that can reverse the neuromuscular manifestations of vincristine sulphate. Convulsions, frequently with hypertension, have been reported in a few patients receiving vincristine. Several instances of convulsions followed by coma have been reported in children.

Eye disorders: Transient cortical blindness and optic atrophy with blindness have been reported.

Ear and labyrinth disorders: Treatment with vinca alkaloids has resulted rarely in both vestibular and auditory damage to the eighth cranial nerve. Manifestations include partial or total deafness, which may be temporary or permanent, and difficulties with balance, including dizziness, nystagmus and vertigo. Particular caution is warranted when vincristine sulphate is used in combination with other agents known to be ototoxic, such as the platinum-containing oncolytics.

Cardiac disorders: Chemotherapy combinations which have included vincristine, when given to patients previously treated with mediastinal radiation, have been associated with coronary artery disease and myocardial infarction. Causality has not been established.

Vascular disorders: Hypertension and hypotension have occurred.

Respiratory, thoracic and mediastinal disorders: Acute shortness of breath and severe bronchospasm have been reported following the administration of vinca alkaloids (see section 4.5). Pharyngeal pain has also been reported.

Gastro-intestinal disorders: Constipation, abdominal cramps, paralytic ileus, diarrhoea, nausea, vomiting, oral ulceration, intestinal necrosis and/or perforation have occurred. The constipation which may be encountered responds well to such usual measures as enemas and laxatives. Constipation may take the form of upper colon impaction and the rectum may be found to be empty on physical examination. Colicky abdominal pain, coupled with an empty rectum, may mislead the clinician. A flat film of the abdomen is useful in demonstrating this condition. A routine prophylactic regimen against constipation is recommended for all patients receiving vincristine sulphate. Paralytic ileus may occur, particularly in young children. The ileus will

reverse itself upon temporary discontinuance of vincristine and with symptomatic care. Parotid gland pain has also been reported.

Skin and subcutaneous tissue disorders: Alopecia, rash.

Musculoskeletal and connective tissue disorders: Muscle wasting, jaw pain, bone pain, back paid, limb pain and myalgias have been reported; pain in these areas may be severe.

Renal and urinary disorders: Polyuria, dysuria and urinary retention due to bladder atony have occurred. Other drugs known to cause urinary retention (particularly in the elderly) should, if possible, be discontinued for the first few days following administration of vincristine.

General disorders and administration site conditions: Fever, headache, injection site reaction (see Section 4.2 Posology and method of administration), slapping gait.

Investigations: Weight loss.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after marketing authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to National Pharmacovigilance Center (NPC).

To report any side effect:

- **Saudi Arabia**

National Pharmacovigilance Center (NPC) SFDA Call center: 19999 E-mail: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa/

- **Other GCC States**

- *Please contact the relevant competent authority.*

4.9 Overdose

Side effects following the use of vincristine are dose related. In children under 13 years of age, death has occurred following doses of vincristine that were 10 times those recommended for therapy. Severe symptoms may occur in this patient group following dosages of 3 to 4 mg/m². Adults can be expected to experience severe symptoms after single doses of 3 mg/m² or more. Therefore, following administration of doses higher than those recommended patients can be expected to experience side-effects in an exaggerated fashion. Supportive care should include the following: (a) prevention of side-effects resulting from the syndrome of inappropriate antidiuretic hormone secretion (this would include restriction of fluid intake and perhaps the administration of a diuretic affecting the function of the loop of Henle and the distal tubule); (b) administration of anticonvulsants; (c) use of enemas or cathartics to prevent ileus (in some instances, decompression of the gastrointestinal tract may be necessary); (d) monitoring the cardiovascular system; (e) determining daily blood counts for guidance in transfusion requirements.

Folinic acid has been observed to have a protective effect in normal mice which were administered lethal doses of vincristine. Isolated case reports suggest that folinic acid may be helpful in treating humans who have received an overdose. A suggested schedule is to

administer 100 mg of folinic acid intravenously every 3 hours for 24 hours and then every 6 hours for at least 48 hours. Theoretical tissue levels of vincristine derived from pharmacokinetic data are predicted to remain significantly elevated for at least 72 hours. Treatment with folinic acid does not eliminate the need for the above-mentioned supportive measures.

Most of an intravenous dose of vincristine is excreted into the bile after rapid tissue binding. Because only very small amounts of the drug appear in dialysate, haemodialysis is not likely to be helpful in cases of overdosage.

Enhanced faecal excretion of parenterally administered vincristine has been demonstrated in dogs pre-treated with cholestyramine. There are no published clinical data on the use of cholestyramine as an antidote in humans.

There are no published clinical data on the consequences of oral ingestion of vincristine. Should oral ingestion occur, the stomach should be evacuated followed by oral administration of activated charcoal and a cathartic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antineoplastic agent - vinca alkaloid. ATC Code: L01C A02

Mechanism of action

Vincristine is an antineoplastic drug with broad-spectrum anti-tumor activity in man. The drug may act by mitotic inhibition, causing an arrest of cell division in metaphase. The drug is relatively marrow-sparing and is thus suitable for use in combination with other cancer chemotherapeutic agents.

5.2 Pharmacokinetic properties

Vincristine is poorly absorbed orally. The clearance of the drug after rapid intravenous injection follows a triphasic decay pattern: a very rapid steep descent (alpha phase); a narrow-middle region (beta-phase) and a much longer terminal region (gamma phase). The terminal phase half-life of the drug varies from 15-155 hours.

Dosing with the drug more frequently than once weekly is therefore probably unnecessary.

Vincristine is primarily excreted by the biliary route.

Patients with impaired hepatic or biliary function, as evidenced by a raised serum alkaline phosphatase, have been shown to have a significantly prolonged vincristine elimination half-life.

5.3 Preclinical safety data

Both *in vivo* and *in vitro* laboratory tests have failed to demonstrate conclusively that this product is mutagenic. No evidence of carcinogenicity was found following intraperitoneal administration in rats and mice, although this study was limited.

In several animal species, vincristine sulphate can include teratogenic effects, as well as embryo lethality, with doses that are non-toxic to the pregnant animal.

As a classic tubulin binder, the primary mode of action of vincristine is aneugenicity, but at higher doses and over prolonged dosing intervals, the expression of clastogenicity becomes a possibility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Water for injections

6.2 Incompatibilities

It is not recommended that vincristine sulphate should be 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. It should not be mixed with anything other than normal saline or 5% glucose solution.

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

6.3 Shelf life

24 months.

Do not use Vincristine sulphate after the expiry date which is stated on the Vial label after EXP: The expiry date refers to the last day of that month.

Chemical and physical in-use stability has been demonstrated for up to 24 hours at 2 – 8 °C and at 25 °C when Vincristine Sulphate injection is diluted with 0.9% sodium chloride solution or 5% glucose solution in infusion bags and protected from light. If stored under normal light at 25 °C, when diluted with 0.9% sodium chloride solution or 5% glucose solution, the diluted product is stable for 8 hours or 4 hours respectively.

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

6.4 Special precautions for storage

Store in a refrigerator (2ºC – 8 ºC).
Keep the vial in the outer carton, in order to protect from light.
For storage conditions after first opening and dilution, see section 6.3.

6.5 Nature and contents of container

1 ml presentation contains 1 mg of vincristine sulphate.

1 ml or 2 ml Type I clear glass vials, with rubber closures and aluminium caps in packs of 5 vials.

6.6 Special precautions for disposal and other handling

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.

Vincristine sulphate can be diluted with sodium chloride 9 mg/ml (0.9%) solution for injection or glucose 50 mg/ml (5%) solution for injection, see section 6.3.

Preparation (Guidelines)

1. Chemotherapeutic agents should be prepared for administration only by professionals who have been trained in the safe use of preparation.

2. Operations such as reconstitution of powder and transfer to syringes should be carried out only in the designated area.

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

4. Pregnant personnel are advised not to handle chemotherapeutic agents.

Contamination

(a) 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.

(b) 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.

7. MARKETING AUTHORISATION HOLDER

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead
SL6 6RJ
UK

MANUFACTURER

Hospira Australia Pty Ltd MULGRAVE, Australia

8. DATE OF RENEWAL OF AUTHORISATION

Date of first authorization: 30-June-1997
Date of latest renewal: 09 March 2020

9. DATE OF REVISION OF THE TEXT

March 2023