140mm

Blasvin 10mg/10ml Injection

(Vinblastine sulphate)

بلاسوِن ۱۰ ملی گرام/۱۰ ملی لیٹر انجیکشن

(وِنبلاسٹن سلفیٹ)

COMPOSITION:
Blasvin Injection 10mg/10ml
Each 10ml vial contains:
Vinblastine sulphate……...10mg
(BP Specifications)

DESCRIPTION
Vinblastine sulfate is the salt of an alkaloid extracted from Vincarosea Linn, a common flowering herb known as the periwinkle.

PHARMACOLOGY
Pharmacodynamics
Vinblastine sulfate has a unique antineoplastic action, distinct from other agents. It disrupts amino acid metabolism from glutamic acid to the citric acid cycle and urea, as shown in tissue-culture studies and supported by in vivo data. It induces a stathmokinetic effect and atypical mitotic figures. However, these cytologic changes don't always correlate with therapeutic (oncolytic) effects.

ADMINISTRATION
Vinblastine sulfate is for intravenous use only and must be administered by professionals experienced with its use. Intrathecal (spinal) administration is fatal. If given intrathecally by mistake, immediate treatment is essential and should begin right after the injection.
1. Remove as much spinal fluid as can be safely done through the lumbar access.
2. Insert a catheter in a lateral cerebral ventricle for the purpose of flushing the subarachnoid space from above with removal through a lumbar access.
3. Initiate flushing through the cerebral catheter with Lactated Ringer's solution infused at the rate of 150 mUh.
4. As soon as fresh frozen plasma becomes available, infuse fresh frozen plasma, 25 ml, diluted in 1 L of Lactated Ringer's solution through the cerebral ventricular catheter at the rate of 75 mUh with removal through the lumbar access. The rate of infusion should be adjusted to maintain a protein level in the spinal fluid of 150 mg/dl.
5. Administer 10 g of glutamic acid intravenously over 24 hours followed by 500 mg 3 times daily by mouth for 1 month or until neurological dysfunction stabilizes. The role of glutamic acid in this treatment is not certain and may not be essential.
The use of this treatment has not been reported following intrathecal vinblastine sulfate.

WARNINGS AND PRECAUTIONS
Vinblastine sulfate should not be diluted with solvents that raise or lower the pH of the resulting solution from between 3.5 and 5. Solutions should be made with normal saline (with or without preservative) and should not be combined in the same container with any other chemical. Unused portions of the remaining solutions that do not contain preservatives should be discarded immediately. The simultaneous oral or intravenous administration of phenytoin and antineoplastic chemotherapy combinations that included vinblastine sulfate has been reported to have reduced blood levels of the anticonvulsant and to have increased seizure activity.
Dosage adjustment should be based on serial blood level monitoring. The contribution of vinblastine sulfate to this interaction is not certain. The interaction may result from either reduced absorption of phenytoin or an increase in the rate of its metabolism and elimination.
Caution should be exercised in patients concurrently taking drugs known to inhibit drug metabolism by hepatic cytochrome P450 isoenzymes in the CYP 3A subfamily, or in patients with hepatic dysfunction. Concurrent administration of vinblastine sulfate with an inhibitor of this metabolic pathway (such as erythromycin, doxorubicin, or etoposide) may cause an earlier onset and/or an increased severity of side effects.
Bone Marrow Metastasis
In patients with malignant-cell infiltration of the bone marrow, the leukocyte and platelet counts have Sometimes fallen precipitously after moderate doses of vinblastine sulfate. Further use of the drug in such patients is inadvisable.
Haematologic
If leukopenia with less than 2,000 white blood cells/mm3 occurs following a dose of vinblastine sulfate, the patient should be watched carefully for evidence of infection until the white-blood-cell count has returned to a safe level.
Pulmonary
Severe bronchospasm and acute shortness of breath have occurred with vinca alkaloids, especially when combined with mitomycin—sometimes appearing within minutes to hours, or up to 2 weeks post-mitomycin. These reactions may require aggressive treatment and are more common in patients with lung issues. If such a reaction occurs, vinblastine should not be readministered. Prolonged daily dosing, even with standard weekly totals, is not recommended due to lack of added benefit and risk of severe toxicity, including seizures, irreversible CNS damage, and death. Strict adherence to the dosage schedule is essential. **Ophthalmic**
Care must be taken to avoid contamination of the eye with concentrations of vinblastine sulfate used clinically. If accidental contamination occurs, severe irritation (or, if the drug was delivered under pressure, even corneal ulceration) may result. The eye should be washed with water immediately and thoroughly.
Hepatic Impairment
Toxicity may be enhanced in the presence of hepatic insufficiency.
Pregnancy
Use of vinblastine sulfate during pregnancy requires caution. Human data are limited, but animal studies indicate potential teratogenic effects, fetal harm, and conceptus resorption. Surviving fetuses may have deformities. No adequate human studies exist. If used during pregnancy or if pregnancy occurs, patients should be warned of fetal risk. Women of childbearing potential should avoid pregnancy.

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Aspermia has been reported in men, and animal studies show metaphase arrest and germ cell degeneration.
Lactation
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from vinblastine sulfate, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Pediatric Use
The dosage schedule for children is indicated under dosage and administration.
Geriatric Use
When cachexia or ulcerated areas of the skin surface are present, there may be a more profound leukopenic response to the drug; therefore, its use should be avoided in older persons suffering from either of these conditions.

WARNINGS
CAUTION:
Only trained professionals should administer vinblastine sulfate. Ensure proper needle placement in the vein before injection, as leakage can cause significant tissue irritation. If extravasation occurs, stop the injection immediately and use a different vein. Local hyaluronidase injection and moderate heat may reduce discomfort and risk of cellulitis.

UNDESIRABLE EFFECTS
Patients should be informed of potential adverse symptoms before using vinblastine sulfate. Adverse reactions are generally dose-related. Most, except for epilation, leukopenia, and neurologic effects, resolve within 24 hours. Neurologic side effects are rare but may persist beyond 24 hours. Leukopenia is the most common and usually dose-limiting reaction.The following are manifestations have been reported as adverse reactions, in decreasing order of frequency:
Hematologic
Leukopenia (granulocytopenia), anemia, thrombocytopenia (myelosuppression).
Ermatologic
Alopecia is common. A single case of light sensitivity associated with this product has been reported.
Dermatologic
Constipation, anorexia, nausea, vomiting, abdominal pain, ileus, vesiculation of the mouth, pharyngitis, diarrhea, hemorrhagic enterocolitis, bleeding from an old peptic ulcer, rectal bleeding.
Neurologic
Numbness of digits (paresthesias), loss of deep tendon reflexes, peripheral neuritis, mental depression, headache, convulsions.
Cardiovascular
Hypertension. Cases of unexpected myocardial infarction and cerebrovascular accidents have occurred in patients undergoing combination chemotherapy with vinblastine, bleomycin and cisplatin. Raynaud's phenomenon has also been reported with this combination.
Pulmonary
See warning and Precautions.
Others
Malaise, bone pain, weakness, pain in tumor-containing tissue, dizziness, jaw pain, skin vesiculation, hypertension, Raynaud's phenomenon when patients are being treated with vinblastine sulfate in combination with bleomycin and cisplatin for testicular cancer. The syndrome of inappropriate secretion of antidiuretic hormone has occurred with higher than recommended doses.
Nausea and vomiting usually may be controlled with ease by antiemetic agents. When epilation develops, it frequently is not total; and, in some cases, hair regrows while maintenance therapy continues.
Extravasation during intravenous injection may lead to cellulitis and phlebitis. If the amount of extravasation is great, sloughing may occur.

OVER DOSAGE
Side effects are dose-dependent and may be more severe with overdosing. No specific antidote exists. Neurotoxicity, similar to vincristine, may occur. As the drug is primarily excreted via the biliary system, toxicity risk increases in patients with liver impairment.

CONTRAINDICATIONS
Vinblastine sulfate is contraindicated in patients who have significant granulocytopenia unless this is a result of the disease being treated. It should not be used in the presence of bacterial infection. Such infections must be brought under control prior to the initiation of therapy with vinblastine sulfate.

STORAGE & INSTRUCTIONS:
Store between 2-8°C.
Protect from sun light and heat.
Keep out of the reach of children.
To be sold on the prescription of a registered oncologist or on demand from cancer hospitals and institutions only.

For Intravenous Use Only. Fatal if given by other routes.

HOW SUPPLIED

10mlx1 Vial

خوراک وطریقہ استعمال:

سرطان کے ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۲-۸ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دوا کو روشنی اور گرمی سے محفوظ رکھیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف مستند انکولوجسٹ یا کینسر ہسپتال کے نسخے پر فروخت کریں۔

Manufactured by:
PHARMASOL PRIVATE LIMITED
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Lahore, Pakistan.

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