

Vinorelbine Injection, USP
Antineoplastic Agent

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form/ Strength	Clinically Relevant Nonmedicinal Ingredients
Intravenous injection	Solution/10 mg vinorelbine base per mL	Water for Injection; Sodium Hydroxide for pH adjustment; no other preservatives or other additives are present.

INDICATIONS AND CLINICAL USE

Vinorelbine Injection, USP (vinorelbine tartrate) is indicated in the treatment of advanced non-small cell lung cancer (NSCLC), as a single agent or in combination.

Vinorelbine Injection is also indicated for the treatment of patients with metastatic breast cancer who have failed standard first-line chemotherapy for metastatic disease. In addition, vinorelbine is indicated for the treatment of patients with metastatic breast cancer who have relapsed within 6 months of anthracycline-based adjuvant therapy.

Vinorelbine is a cytotoxic drug and should be used only by physicians experienced with cancer chemotherapeutic drugs. Blood counts should be taken prior to each dose. The dosage should be reduced or the drug discontinued upon evidence of abnormal depression of the bone marrow.

Geriatrics (> 65 years of age): Evidence from clinical studies and experience suggests that use in the geriatric population is not associated with differences in safety or effectiveness and a brief discussion can be found in the appropriate sections (see **WARNINGS AND PRECAUTIONS**).

Pediatrics (≤ 16 years of age): Safety and effectiveness in children have not been established.

CONTRAINDICATIONS

Vinorelbine Injection, USP is contraindicated in patients with known hypersensitivity to vinorelbine.

As with other vinca alkaloids, vinorelbine is contraindicated in patients who have drug-induced severe granulocytopenia or severe thrombocytopenia.

WARNINGS AND PRECAUTIONS

<p align="center">Serious Warnings and Precautions</p>
<ul style="list-style-type: none"> • Vinorelbine Injection, USP is a cytotoxic drug and should be used only by physicians experienced with cancer chemotherapeutic agents (see INDICATIONS AND CLINICAL USE). • Blood counts should be taken prior to each dose. The dosage should be reduced or the drug discontinued upon evidence of abnormal depression of the bone marrow. • This preparation is for intravenous administration only. Intrathecal administration of other vinca alkaloids has resulted in death. Syringes containing this product should be labelled "WARNING – FOR INTRAVENOUS USE ONLY. FATAL if given intrathecally."

General

Vinorelbine Injection, USP is for intravenous use only. Vinorelbine is a moderate vesicant and can produce phlebitis or extravasation injury. Inadequate flushing of the vein after peripheral administration may increase the risk of phlebitis.

It is extremely important that the needle be properly positioned in the vein before this product is injected. If leakage into surrounding tissue should occur during intravenous administration of vinorelbine, it may cause severe irritation. The injection should be discontinued immediately, and any remaining portion of the dose should then be introduced into another vein.

In all instances where the use of vinorelbine is considered for chemotherapy, the physician must evaluate the need and usefulness of the drug against the risk of adverse

events. Most drug-related adverse reactions are reversible. If severe adverse events occur, the drug should be reduced in dosage or discontinued, and appropriate corrective measures should be taken based on the clinical judgment of the physician. Reinstitution of therapy with vinorelbine should be carried out with caution and alertness as to possible recurrence of toxicity.

Vinorelbine should be used with extreme caution in patients whose bone marrow reserve may have been compromised by prior irradiation or chemotherapy, or whose marrow function is recovering from previous chemotherapy.

Administration of vinorelbine to patients with prior radiation therapy may result in radiation recall reactions (see **DRUG INTERACTIONS**).

Information for Patients

Patients should be informed that vinorelbine is a vesicant and can produce phlebitis or extravasation injury, and that the major acute toxicities of vinorelbine are related to bone marrow toxicity, specifically granulocytopenia with increased susceptibility to infection, and neuropathy. They should also be advised to report fever or chills immediately. Vinorelbine should not be used in pregnancy unless the physician feels the potential benefit justifies the risk of potential harm to the fetus.

Hematologic

A low incidence of death (1%) due to neutropenic sepsis has been reported (see **ADVERSE REACTIONS**). Bone marrow toxicity, specifically granulocytopenia, is dose-limiting. Complete blood counts with differentials should be performed and results reviewed prior to each dose of vinorelbine. Vinorelbine should not be administered to patients with granulocyte counts < 1,000 cells/mm³. Patients developing severe granulocytopenia should be monitored carefully for evidence of infection and/or fever (see **DOSAGE AND ADMINISTRATION**).

Hepatic/Biliary/Pancreatic

There is no evidence that the toxicity of vinorelbine is enhanced in patients with elevated liver enzymes; no data are available for patients with severe baseline cholestasis. However, pharmacologic evidence suggests that the liver plays an important role in the metabolism of vinorelbine. Although there are no data available from patients with severe liver disease, caution should be exercised when administering vinorelbine to patients with severe hepatic injury or impairment.

Neurologic

Patients with a prior history or pre-existing neuropathy, regardless of etiology, should be monitored for new or worsening signs and symptoms of neuropathy while receiving vinorelbine.

Ophthalmologic

Care must be exercised to avoid contamination of the eye with vinorelbine. Accidental exposure should be treated immediately with a large volume of irrigation solution (water or sodium chloride).

Respiratory

Acute shortness of breath and severe bronchospasm have been reported infrequently following the administration of vinorelbine and of other vinca alkaloids. These events have been encountered most commonly when the vinca alkaloid was used in combination with mitomycin and may require aggressive treatment, particularly when there is pre-existing pulmonary dysfunction. Bronchodilators, steroids and/or oxygen have produced symptomatic relief.

Special Populations

Pregnant Women: There are no studies in pregnant women. Vinorelbine has been shown to be embryotoxic and/or fetotoxic in animals. Vinorelbine should not be used in pregnancy.

Nursing Women: It is not known whether the drug is excreted in human milk. Because many drugs are excreted in human milk and because of its potential for serious adverse reactions in nursing infants, it is recommended that nursing be discontinued in women who are receiving therapy with vinorelbine.

Pediatrics (≤ 16 years of age): Safety and effectiveness in children have not been established.

Geriatrics (> 65 years of age): Of the total number of patients in North American clinical studies of intravenous vinorelbine, approximately one-third were 65 years of age or greater. No overall differences in effectiveness or safety were observed between these patients and younger patients. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Monitoring and Laboratory Tests

Since dose-limiting clinical toxicity is the result of depression of the white blood cell count, it is imperative that complete blood counts with differentials be obtained prior to each dose of vinorelbine (see **ADVERSE REACTIONS, Clinical Trial Adverse Drug Reactions, Hematologic**).

ADVERSE REACTIONS

Clinical Trial Adverse Drug Reactions

Data in the following tables are based on the experience of 365 patients (143 patients with NSCLC; 222 patients with advanced breast cancer) for whom a complete safety database was available and who were treated with vinorelbine as a single agent in three

North American trials (one NSCLC trial and two advanced breast cancer trials). Patients treated for breast cancer were allowed to have received adjuvant chemotherapy in both trials, and in one, up to two prior regimens for advanced disease. The dosing schedule was 30 mg/m² intravenous vinorelbine on a weekly basis.

Hematology		ABC (%)	NSCLC (%)
Granulocytopenia	< 2,000 cells/mm ³	96	80
	< 500 cells/mm ³	41	28
Leukopenia	< 4,000 cells/mm ³	99	81
	< 1,000 cells/mm ³	16	12
Thrombocytopenia	< 100,000 cells/mm ³	6	4
	< 50,000 cells/mm ³	< 1	1
Anemia	< 11 g/dL Hgb	87	77
	< 8 g/dL Hgb	14	1
Hospitalizations due to granulocytopenic complications		9	8

Clinical Chemistry Elevations	% Incidence All Grades		% Incidence Grade 3		% Incidence Grade 4	
	ABC	NSCLC	ABC	NSCLC	ABC	NSCLC
Total Bilirubin NSCLC : n = 137 ABC : n = 214	14	9	4	3	3	2
SGOT NSCLC : n = 133 ABC : n = 213	74	54	7	2	< 1	1

ABC = Advanced Breast Cancer; NSCLC = Non-Small Cell Lung Cancer
^a Grade based on modified criteria of the National Cancer Institute
^b Patients with NSCLC had not received prior chemotherapy. The majority of patients with advanced breast cancer had received prior chemotherapy.

Adverse Event	% Incidence All Grades		% Incidence Grade 3		% Incidence Grade 4	
	ABC n=222	NSCLC n=143	ABC n=222	NSCLC n=143	ABC n=222	NSCLC n=143
General						
Injection site reaction	21	38	1	5	0	0
Asthenia	41	25	8	5	0	0
Pain	16	15	3	2	0	0
Pain at injection site	18	13	3	1	0	0
Fever	19	10	1	0	0	1
Pain (Abdomen)	12	6	1	1	0	0
Pain (Chest)	8	5	1	2	0	0
Phlebitis	5	10	0	1	0	0
Digestive System						
Nausea	50	33	3	1	0	0
Constipation	38	28	3	2	0	0
Anorexia	19	16	< 1	2	0	0
Stomatitis	16	15	0	0	0	0
Vomiting	23	14	2	1	0	0
Diarrhea	20	13	< 1	1	0	0
Musculoskeletal System						
Myasthenia	9	5	2	1	< 1	0
Nervous System						
Paresthesia	20	11	0	1	0	0
Hypoesthesia	11	10	< 1	0	< 1	0
Respiratory System						
Dyspnea	9	3	1	2	1	0
Skin and Appendages						
Alopecia	12	12	0	1	0	0
Rash	5	5	0	0	0	0

ABC = Advanced Breast Cancer; NSCLC = Non-Small Cell Lung Cancer
^a Grade based on modified criteria of the National Cancer Institute
^b Patients with NSCLC had not received prior chemotherapy. The majority of patients with advanced breast cancer had received prior chemotherapy.

Hematologic: Granulocytopenia was the major dose-limiting toxicity with vinorelbine; it was generally reversible and not cumulative over time. Granulocyte nadirs occurred 7 to 10 days after the dose and usually recovered within the following 7 to 14 days. Granulocytopenia resulted in hospitalizations for fever and/or sepsis in 8% of NSCLC and 9% of breast cancer patients. Septic deaths occurred in approximately 1% of patients.

Grade 3 or 4 anemia occurred in 1% of lung cancer and 14% of breast cancer patients. Blood products were administered to 18% of patients who received vinorelbine. The incidence of Grade 3 and 4 thrombocytopenia was less than 1%.

Neurologic: Mild to moderate peripheral neuropathy manifested by paresthesia and hypoesthesia were the most frequently reported neurologic toxicities (10 to 20%, see Table 2). Loss of deep tendon reflexes occurred in less than 5% of patients. The development of severe peripheral neuropathy was unusual.

Dermatologic: Alopecia was reported in only 12% of patients and was usually mild. Vinorelbine is a moderate vesicant. Injection site reactions, including erythema, pain at injection site, and vein discoloration occurred in approximately one-third of all patients; 2% were severe. Chemical phlebitis along the vein proximal to the site of injection was reported.

Gastrointestinal: Mild or moderate nausea occurred in 32% of NSCLC and 47% of breast cancer patients treated with vinorelbine. Severe nausea was infrequent (1% and 3% in NSCLC and breast cancer patients respectively). Prophylactic administration of antiemetics was not routine in patients treated with single-agent vinorelbine. Constipation occurred in approximately 28% of NSCLC and 38% of breast cancer patients, with paralytic ileus occurring in less than 2% of patients. Vomiting, diarrhea, anorexia, and stomatitis were usually mild or moderate and occurred in less than 20% of patients.

Hepatic: Transient elevations of liver enzymes were reported without clinical symptoms.

Cardiovascular: Chest pain was reported in 5% of NSCLC and 8% of breast cancer patients. Most reports of chest pain were in patients who had either a history of cardiovascular disease or tumour within the chest. There have been rare reports of myocardial infarction; however, these have not been shown definitely attributable to vinorelbine.

Pulmonary: Shortness of breath was reported in 3% of NSCLC and 9% of breast cancer patients; and was severe in 2% of each patient population. Interstitial pulmonary changes have been documented in a few patients.

Other: Asthenia occurred in approximately 25% of patients with NSCLC and 41% of patients with breast cancer. It was usually mild or moderate but tended to increase with cumulative dosing.

Other toxicities that have been reported in ≤ 5% of patients include jaw pain, myalgia, arthralgia, headache, dysphagia, and rash. Hemorrhagic cystitis and the syndrome of inappropriate ADH secretion were each reported in < 1% of patients. The treatment of these entities are mainly symptomatic. The treatment of hemorrhagic cystitis is i.v. fluids for forced diuresis and/or irrigation of bladder. For the treatment of SIADH, please refer to the major textbooks of medicine.

Observed During Clinical Practice

In a randomized study in NSCLC patients, 206 patients received treatment with vinorelbine plus cisplatin and 206 patients received single-agent vinorelbine. The incidence of severe nausea and vomiting was 30% for vinorelbine/cisplatin compared to < 2% for single-agent vinorelbine. Cisplatin did not appear to increase the incidence of neurotoxicity observed with single-agent vinorelbine. However, myelosuppression, specifically Grade 3 and 4 granulocytopenia, was greater with the combination of vinorelbine/cisplatin (79%) than with single-agent vinorelbine (53%). The incidence of fever and infection may be increased with the combination.

Postmarket Adverse Drug Reactions

In addition to adverse events reported from clinical trials, the following events have been identified during postmarketing use of vinorelbine. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to combination of their seriousness, frequency of reporting, or potential causal connection to vinorelbine or a combination of these factors.

Body as a Whole: Systemic allergic reactions reported as anaphylaxis, pruritis, urticaria and angioedema, flushing and radiation recall events such as dermatitis and esophagitis (see **WARNINGS AND PRECAUTIONS**) have been reported.

Hematologic: Thromboembolic events including pulmonary embolus and deep venous thrombosis have been reported primarily in seriously ill and debilitated patients with known predisposing risk factors for these events.

Neurologic: Peripheral neurotoxicities such as, but not limited to, muscle weakness and disturbance of gait have been observed in patients with and without prior symptoms. Vestibular and auditory deficits have been observed with vinorelbine, usually when used in combination with cisplatin. There may be increased potential for neurotoxicity in patients with pre-existing neuropathy, regardless of etiology, who receive vinorelbine. Patients who receive vinorelbine and paclitaxel, either concomitantly or sequentially, should be monitored for signs and symptoms of neuropathy (see **WARNINGS AND PRECAUTIONS**).

Skin: Injection site reactions, including localised rash and urticaria, blister formation and skin sloughing have been observed in clinical practice. Some of these reactions may be delayed in appearance.

Gastrointestinal: Dysphagia and mucositis have been reported.

Cardiovascular: Hypertension, hypotension, vasodilation, tachycardia, and pulmonary edema have been reported.

Pulmonary: Pneumonia has been reported.

Vinorelbine can produce acute and subacute pulmonary reactions. The acute reaction usually resembles an allergic event and may respond to bronchodilators. Subacute pulmonary reactions occur shortly after drug administration and may be characterized by cough, dyspnea, hypoxemia, and interstitial infiltration. Subacute pulmonary reactions may respond to corticosteroid therapy.

Musculoskeletal: Headache has been reported with and without other musculoskeletal aches and pains.

Other: Pain in tumour-containing tissue, back pain and abdominal pain have been reported. Electrolyte abnormalities, including hyponatremia consistent with the syndrome of inappropriate ADH secretion, have been reported in seriously ill and debilitated patients.

Combination Use: Patients with prior exposure to paclitaxel and who have demonstrated neuropathy should be monitored closely for new or worsening neuropathy. Patients who have experienced neuropathy with previous drug regimens should be monitored for symptoms of neuropathy while receiving vinorelbine.

Vinorelbine may result in radiosensitising effects with prior or concomitant radiation therapy (see **WARNINGS AND PRECAUTIONS**).

DRUG INTERACTIONS

Drug-Drug Interactions

Acute pulmonary reactions have been reported with vinorelbine and other vinca alkaloids used in conjunction with mitomycin (see **WARNINGS AND PRECAUTIONS, Respiratory**). Vinorelbine should be administered with caution in combination with mitomycin.

Although the pharmacokinetics of vinorelbine are not influenced by the concurrent administration of cisplatin, the incidence of toxicities, specifically granulocytopenia, high frequency hearing loss and tinnitus, with the combination of vinorelbine and cisplatin, are higher than with single-agent vinorelbine.

Patients who receive vinorelbine and paclitaxel, either concomitantly or sequentially, should be monitored for signs and symptoms of neuropathy. Administration of vinorelbine to patients with prior or concomitant radiation therapy may result in radiosensitising effects.

DOSAGE AND ADMINISTRATION

Dosing Considerations

Safety issues to consider when developing the dosage regimen for individual patients include the following:

- hematologic toxicity
- hepatic insufficiency

Recommended Dose and Dosage Adjustment

The usual initial dose of Vinorelbine Injection, USP is 30 mg/m² administered weekly. The recommended method of administration is an intravenous injection over 6 to 10 minutes. In controlled trials, single-agent vinorelbine was given weekly until progression or dose-limiting toxicity.

No dose adjustments are required for renal insufficiency. If moderate or severe neurotoxicity develops, vinorelbine should be discontinued. The dosage should be adjusted according to hematologic toxicity or hepatic insufficiency.

Dose Modifications for Hematologic Toxicity: Granulocyte counts should be $\geq 1,000$ cells/mm³ prior to the administration of vinorelbine. In the referenced North American trial, in which hematologic adverse events were observed, the following dose adjustment scheme was employed and should be followed in patients receiving vinorelbine.

Table 3: Dose Adjustments Based on Granulocyte Counts	
Granulocytes (cells/mm ³) on Days of Treatment	Dose of Vinorelbine (mg/m ²)
$\geq 1,500$	30
1,000 to 1,499	15
< 1,000	Do not administer. Repeat granulocyte count in 1 week. If granulocyte count is < 1,000 cells/mm ³ for > 3 weeks, discontinue vinorelbine.

Note: For patients who, during treatment with vinorelbine, have experienced fever and/or sepsis while granulocytopenic or required a delay in dosing of up to 3 weeks due to granulocytopenia, the dose of vinorelbine should be:
22.5 mg/m² for granulocytes $\geq 1,500$ cells/mm³.
11.25 mg/m² for granulocytes 1,000 to 1,499 cells/mm³.

Vinorelbine should be administered with caution to patients with hepatic insufficiency. In patients who develop hyperbilirubinemia during treatment with vinorelbine, the dose should be adjusted for total bilirubin.

Administration

Vinorelbine Injection should be administered by individuals experienced in the administration of cancer chemotherapeutic drugs.

This preparation is for intravenous administration only. Intrathecal administration of other vinca alkaloids has resulted in death. Syringes containing this product should be labelled "WARNING – FOR INTRAVENOUS USE ONLY. FATAL if given intrathecally."

Administrative Precautions:

Vinorelbine must be administered intravenously. It is extremely important that the intravenous needle or catheter be properly positioned before any vinorelbine is injected. Leakage into surrounding tissue during intravenous administration of vinorelbine may cause considerable irritation, local tissue necrosis and/or thrombophlebitis. If extravasation occurs, the injection should be discontinued immediately, and any remaining portion of the dose should then be introduced into another vein. The application of moderate heat to the area of leakage in the form of warm compress applied for 15 to 20 minutes at least four times per day for the first 24 to 48 hours in addition to rest and elevation of the affected site for 48 - 72 hours has been reported to help disperse drug and minimize discomfort associated with the extravasation of other vinca alkaloids.

Preparation for Administration:

Vinorelbine Injection must be diluted in either a syringe or i.v. bag using one of the recommended solutions. The diluted vinorelbine should be administered over 6 to 10 minutes into the side port of a free-flowing i.v. followed by flushing with at least 75 to 125 mL of one of the solutions. For diluents that may be used, see **Dilution** below.

Syringe: The calculated dose of vinorelbine should be diluted to a concentration between 1.5 and 3.0 mg/mL.

IV Bag: The calculated dose of vinorelbine should be diluted to a concentration between 0.5 and 2.0 mg/mL.

Dilution

Syringe: Vinorelbine Injection diluted to a concentration between 1.5 and 3.0 mg/mL may be used for up to 24 hours when stored in polypropylene syringes between 5 and 30°C. The following solutions may be used for dilution:

- 5% Dextrose Injection, USP
- 0.9% Sodium Chloride Injection, USP

IV Bag: Vinorelbine Injection diluted to a concentration between 0.5 and 2.0 mg/mL may be used for up to 24 hours when stored in polyvinylchloride bags between 5 and 30°C. The following solutions may be used for dilution:

- 5% Dextrose Injection, USP
- 0.9% Sodium Chloride Injection, USP
- 0.45% Sodium Chloride Injection, USP
- 5% Dextrose and 0.45% Sodium Chloride Injection, USP
- Ringer's Injection, USP
- Lactated Ringer's Injection, USP

As with all the parenteral drug products, intravenous admixtures should be inspected visually for clarity of solutions, particulate matter, precipitate, discoloration, and leakage prior to administration, whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate, discoloration or leakage should not be used. Any unused portion should be discarded.

OVERDOSAGE

The primary anticipated complications of overdosage would consist of bone marrow suppression and peripheral neurotoxicity.

There is no known antidote for vinorelbine overdosage. Overdoses involving quantities up to ten times the recommended dose (30 mg/m²) have been reported. The toxicities described were consistent with those listed in the **ADVERSE REACTIONS** section including paralytic ileus, stomatitis, and esophagitis. Bone marrow aplasia, sepsis, and paresis have also been reported. Fatalities have occurred following overdose of vinorelbine. If overdosage occurs, general supportive measures together with appropriate blood transfusions, growth factors and antibiotics should be instituted as deemed necessary by the physician.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

Vinorelbine is a novel vinca alkaloid which interferes with microtubule assembly. Vinca alkaloids are structurally similar compounds comprising of two multiringed units, vindoline and catharanthine. Vinorelbine is a vinca alkaloid in which the catharanthine unit is the site of structural modification. This structural change imparts unique pharmacologic properties which may translate into clinical benefits for patients with various malignancies. The antitumour activity of vinorelbine is thought to be due primarily to inhibition of mitosis at metaphase through its interaction with tubulin. Vinorelbine may also interfere with amino acid, cyclic AMP, and glutathione metabolism; calmodulin-dependent Ca⁺⁺-transport ATPase activity; cellular respiration; and nucleic acid and lipid biosynthesis.

Pharmacokinetics

Following intravenous administration, vinorelbine concentration in plasma decays in a triphasic manner. The initial rapid decline represents distribution of drug to peripheral compartments and metabolism of the drug. The prolonged terminal phase is due to relatively slow efflux of vinorelbine from peripheral compartments. The terminal phase half-life averaged 27.7 to 43.6 hours; the mean plasma clearances ranged from 0.97 to 1.26 L/hr/kg; and steady state volume of distribution (V_{ss}) values ranged from 25.4 to 40.1 L/kg.

The disposition of radiolabelled vinorelbine has been studied in a limited number of patients. Approximately 18% of the administered dose was recovered in the urine and 46% in the feces. Incomplete recovery in humans is consistent with results in animals. A separate study of the urinary excretion of vinorelbine showed that $10.9\% \pm 0.7\%$ of a 30 mg/m² intravenous dose was excreted unchanged in the urine.

One metabolite of vinorelbine, deacetylvinorelbine, has been shown to possess anti-tumour activity. This metabolite has been detected but not quantified in human plasma. The effects of renal or hepatic dysfunction on the disposition of vinorelbine have not been assessed.

The pharmacokinetics of vinorelbine are not influenced by the concurrent administration of cisplatin with vinorelbine (see **DRUG INTERACTIONS**).

STORAGE AND STABILITY

Store Vinorelbine Injection, USP vials between 2 and 8°C in the original package. Protect from light and freezing. Single-dose vials. Discard unused portion.

Vinorelbine Injection is initially clear and colourless to pale yellow, but may develop a slightly darker yellow to light amber colour in time. This does not indicate a change which should preclude its use. Parenteral drug products should be visually inspected for particulate matter and discoloration prior to administration whenever solution and container permit. If particulate matter is seen, Vinorelbine Injection should not be administered.

Syringe: Vinorelbine Injection diluted to a concentration between 1.5 and 3.0 mg/mL may be used for up to 24 hours when stored in polypropylene syringes between 5 and 30°C.

IV Bag: Vinorelbine Injection diluted to a concentration between 0.5 and 2.0 mg/mL may be used for up to 24 hours when stored in polyvinylchloride bags between 5 and 30°C.

As with all the parenteral drug products, intravenous admixtures should be inspected visually for clarity of solutions, particulate matter, precipitate, discoloration, and leakage prior to administration, whenever solution and container permit. Solutions showing haziness, particulate matter, precipitate, discoloration or leakage should not be used. Any unused portion should be discarded.

SPECIAL HANDLING INSTRUCTIONS

Since vinorelbine is a cytostatic agent, established procedures specific to the handling and use of such agents must be followed.

As with other toxic compounds, caution should be exercised in handling and preparing the solution of vinorelbine. Skin reactions may occur with accidental exposure. The use of gloves is recommended. If the solution of vinorelbine contacts the skin or mucosa, immediately wash the skin or mucosa thoroughly with soap and water. Severe irritation of the eye has been reported with accidental contamination of the eye with another vinca alkaloid. If this happens with vinorelbine, the eye should be washed with water immediately and thoroughly.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Vinorelbine Injection, USP consists of an aqueous solution of vinorelbine tartrate, equivalent to 10 mg vinorelbine base per millilitre of solution. Sodium hydroxide may be used for pH adjustment. No other preservatives or other additives are present. Vinorelbine Injection is a clear, colourless to pale yellow solution in Water for Injection, USP.

Vinorelbine Injection is supplied in clear, colourless glass vials as a solution of 10 mg/mL vinorelbine base in 1 mL and 5 mL single-dose vials.

Product Codes

CP081101 1 mL fill in a 2 mL vial, packaged individually

CP081105 5 mL fill in a 5 mL vial, packaged individually

Vial stoppers do not contain natural rubber latex.

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