



SAGENT Pharmaceuticals™

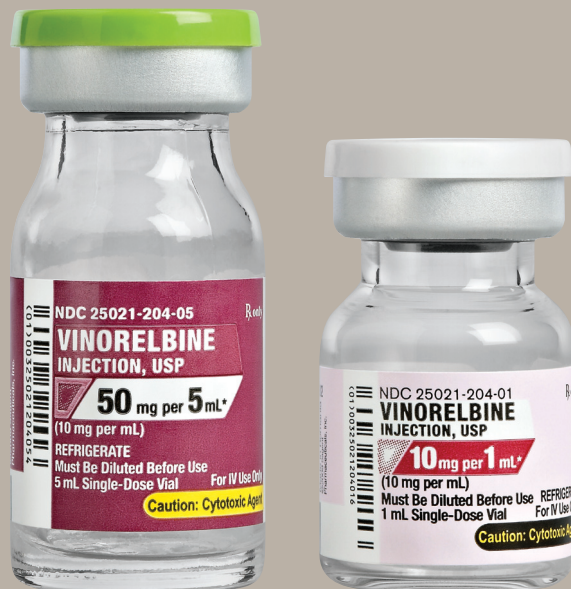
VINORELBINE

CATALOG

VINORELBINE Injection, USP

SAGENT delivers injectables excellence in oncology

- Available in:
 - 10 mg per 1 mL single-dose vials
 - 50 mg per 5 mL single-dose vials
 - LATEX-FREE
 - Preservative-free
 - Discover **PreventIV Measures™** packaging features:
 - Easy-to-read drug name and dosage strength
 - Bar codes included on the vials and cartons for ease of scanning
 - Unique label design
 - Yellow and black cytotoxic warning flag designed to caution healthcare workers who handle the product
- Enhanced packaging and labeling designed to promote safety and help reduce medication errors



Please see full prescribing information for VINORELBINE Injection, USP, enclosed.



Discover Injectables Excellence™

VINORELBINE Injection, USP



Brand Name Equivalent: NAVELBINE

NDC Number	Description	Strength	Vial Closure	Unit of Sale	Bar Coded
25021-204-01	Glass Vial	10 mg per 1 mL	20 mm	1 Vial	✓
25021-204-05	Glass Vial	50 mg per 5 mL	20 mm	1 Vial	✓

These SAGENT products meet stringent FDA requirements and are AP rated, LATEX-FREE and preservative-free.

To order, or for more information about discovering Injectables Excellence with SAGENT, contact your sales representative, call 1-866-625-1618 or visit www.SagentPharma.com.

Listening. Responding. Delivering. That's Injectables Excellence. That's SAGENT Pharmaceuticals.

Vinorelbine Injection, USP

INDICATIONS

Vinorelbine is indicated as a single agent or in combination with cisplatin for the first-line treatment of ambulatory patients with unresectable, advanced nonsmall cell lung cancer (NSCLC).

IMPORTANT SAFETY INFORMATION

WARNINGS

Vinorelbine Injection, USP should be administered under the supervision of a physician experienced in the use of cancer chemotherapeutic agents. This product is for intravenous (IV) use only. Intrathecal administration of other vinca alkaloids has resulted in death. Syringes containing this product should be labeled "WARNING – FOR IV USE ONLY. FATAL if given intrathecally." Severe granulocytopenia resulting in increased susceptibility to infection may occur. Granulocyte counts should be $\geq 1,000$ cells/mm³ prior to the administration of vinorelbine. The dosage should be adjusted according to complete blood counts with differentials obtained on the day of treatment. Caution – It is extremely important that the intravenous needle or catheter be properly positioned before vinorelbine is injected. Administration of vinorelbine may result in extravasation causing local tissue necrosis and/or thrombophlebitis (see DOSAGE AND ADMINISTRATION: Administration Precautions).

- Patients treated with Vinorelbine Injection, USP should be frequently monitored for myelosuppression both during and after therapy. Patients developing severe granulocytopenia should be monitored carefully for evidence of infection and/or fever.
- Acute shortness of breath and severe bronchospasm have been reported infrequently, following the administration of vinorelbine and other vinca alkaloids, most commonly when the vinca alkaloid was used in combination with mitomycin.
- Fatal cases of interstitial pulmonary changes and acute respiratory distress syndrome (ARDS) occurred in patients treated with single-agent vinorelbine.
- Vinorelbine has been reported to cause severe constipation, paralytic ileus, intestinal obstruction, necrosis, and/or perforation.
- Vinorelbine may cause fetal harm if administered to a pregnant woman.

CONTRAINDICATIONS

Administration of Vinorelbine Injection, USP is contraindicated in patients with pretreatment granulocyte counts $< 1,000$ cells/mm³.

PRECAUTIONS

- 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 the effects of previous chemotherapy.
- Administration of vinorelbine to patients with prior radiation therapy may result in radiation recall reactions.
- 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.
- Care must be taken to avoid contamination of the eye with concentrations of vinorelbine used clinically.
- Caution should be exercised when administering vinorelbine to patients with severe hepatic injury or impairment.
- Caution should be exercised in patients concurrently taking drugs known to inhibit drug metabolism by hepatic cytochrome P450 isoenzymes in the CYP3A subfamily.
- It is not known whether vinorelbine is excreted in human milk.
- Safety and effectiveness of vinorelbine in pediatric patients have not been established.

ADVERSE REACTIONS

Most drug-related adverse events of vinorelbine are reversible. If severe adverse events occur, vinorelbine should be reduced in dosage or discontinued and appropriate corrective measures taken. The most common adverse events include myelosuppression (granulocytopenia, leukopenia, and anemia), nausea, constipation, injection site reactions, and peripheral neuropathy. Other commonly reported adverse events include systemic allergic reactions, thromboembolic events, peripheral neurotoxicities, dysphagia, mucositis, pneumonia, and headache.

OVERDOSAGE

There is no known antidote for overdoses 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.

Please see full prescribing information for Vinorelbine Injection, USP.



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