Vinblastine Sulfate for Injection USP

WARNING

Caution — This preparation should be administered only by individuals experienced in the administration of vinca alkaloids. It is extremely important that the intravenous needle or catheter be properly positioned before any vinblastine sulfate is injected. Leakage into surrounding tissue during intravenous administration of vinblastine sulfate may cause considerable irritation. If extravasation occurs, the injection should be discontinued immediately and any remaining portion of the dose should be intramuscularly injected into another wellperfused area.

.brand name, lot number, fill volume, date, expiration date, and net contents are on the vial label. Do not fill more than 3.5 mL of the injectable solution into a tuberculin syringe. Do not inject the contents of a multiple-dose vial into the same site of the body more than once.

The structural formula is as follows:

\[
\text{C}_{46}\text{H}_{58}\text{O}_{9}\text{N}_{4} \cdot \text{H}_{2}\text{SO}_{4}
\]

Vinblastine sulfate is a white to off-white crystalline powder. It is freely soluble in water, readily soluble in methanol, and slightly soluble in ethanol. It is insoluble in benzene, ether, and acetone.

The clinical formulation is supplied in a sterile form for intravenous use only. Vials of Vinblastine Sulfate for Injection USP contain 10 mg (0.10 mmol) of vinblastine sulfate. The solution is buffered with sodium chloride and contains 0.1 mL sodium hydroxide. The solution is not for intrathecal use. Do not fill more than 3.5 mL of the injectable solution into a tuberculin syringe. Do not inject the contents of a multiple-dose vial into the same site of the body more than once.

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Carcinogenesis, Mutagenesis, Impairment of Fertility:

In studies of this group of drugs on mice and hamsters, increased incidences of neoplastic diseases have been reported. In one study, tumors of the liver were found at an incidence over controls in another study.

The group of drugs causing slightly increased or the same tumor incidence as controls in one study and 1.5 to 2-fold increase in tumor incidence over controls in another study. It has been reported that a significant number of the tumors were of the liver.

Tests using hamster lung cells in culture have produced chromosomal changes, including chromatid breaks and exchanges, in the translocation carrier. The offspring of these mice were not heterozygous translocation carriers.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Tests using another type of hamster cell failed to demonstrate mutation. Breaks and aberrations were not observed on chromosome preparations.

Tests using another type of hamster cell failed to demonstrate evidence of carcinogenesis when the animals were treated with the maximum tolerated dose and with one-half the maximum tolerated dose. Tests using another type of hamster cell failed to demonstrate clearly evidence of carcinogenesis when the animals were treated with the maximum tolerated dose and with one-half dose that the same dose that was given by rapid intravenous injection. The intramedullary lethal dose is 10 mg/kg body weight; the LD₅₀ oral is 100 to 150 mg/kg body weight.

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