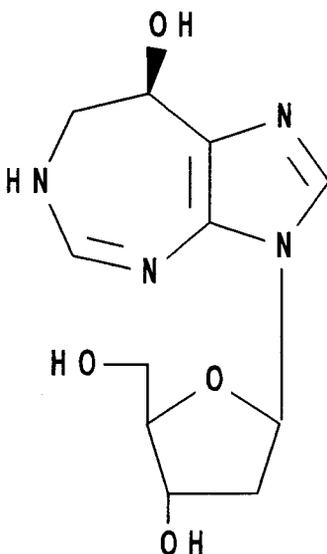


# PENTOSTATIN

NSC - 218321



**Chemical Name:** 3-(2-Deoxy-β-D-erythro-pentofuranosyl)-3,6,7,8-tetrahydroimidazo[4,5-d][1,3]diazepin-8-ol, (R)-

**Other Names:** 2'-Deoxycoformycin, Co-Vidarabine, Nipent, Pentostatin (USAN)

**CAS Registry Number:** 53910-25-1

**Molecular Formula:** C<sub>11</sub>H<sub>16</sub>N<sub>4</sub>O<sub>4</sub>

**M.W.:** 268.3

**How Supplied:** For injection, 10 mg, vial: supplied as a lyophilized powder with 50 mg mannitol, USP, and sodium hydroxide to adjust the pH in 5 mL flint vials.

**Solution Preparation:** 10 mg/vial: When constituted with 5 mL of 0.9% Sodium Chloride Injection, USP, each milliliter contains 2 mg of pentostatin and 10 mg of mannitol, USP, at pH 6.7 to 8.7.

**Storage:** Refrigerate the intact vials (2-8 °C).

**Stability:** Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for 5 years under refrigeration but have gone below 90% of labeled amount by 3 years storage at room temperature (22-25 °C). Intact vials are unstable when stored at elevated temperature (50 °C) for one year. The intact vials bear a "do not use after" date.

Constitution with 0.9% Sodium Chloride Injection, USP, results in a solution which is chemically stable at room temperature (22-25 °C) for at least 72 hours, exhibiting about 2 to 4% decomposition.

When diluted to a concentration of 10 mg per 500 mL in 0.9% Sodium Chloride Injection, USP, or Lactated Ringer's Injection, USP, pentostatin is chemically stable for at least 48 hours at room temperature (22-25 °C), exhibiting approximately 0 to 4% decomposition.

At a concentration of 10 mg per 500 mL in 5% Dextrose Injection, USP, approximately 2% decomposition occurs in 24 hours at room temperature. As much as 8 to 10% loss has been reported to occur in 48 hours.

No potency loss was detected in the constituted solution or in admixtures in 5% Dextrose Injection, USP, or 0.9% Sodium Chloride Injection, USP, when refrigerated at 5 °C over 96 hours.

**CAUTION:** This single-use product contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

**Route of Administration:** Intravenous