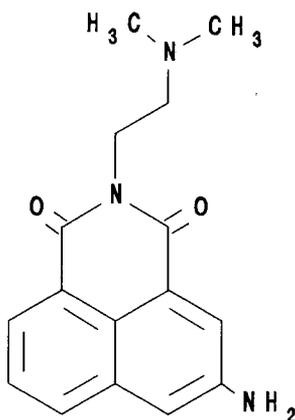


# AMONAFIDE

NSC - 308847



**Chemical Name:** 5-Amino-2-[2-(dimethylamino)ethyl]-  
1H-benz[de]isoquinoline-1,3(2H)-dione

**Other Names:** Nafidimide, Amonafide HCl (USAN)  
(NSC-621093)

**CAS Registry Number:** 69408-81-7

**Molecular Formula:** C<sub>16</sub>H<sub>17</sub>N<sub>3</sub>O<sub>2</sub>

**M.W.:** 283.3

**How Supplied:** Sterile, 500 mg (as the base), vial: supplied as a yellow to orange or red-orange lyophilized powder with sodium hydroxide to adjust pH in 30 mL flint vials.

**Solution Preparation:** 500 mg/vial: Constitution with 9.6 mL of Sterile Water for Injection, USP, or 0.9% Sodium Chloride Injection, USP, results in a solution containing 50 mg/mL of amonafide with sodium hydroxide to adjust to pH 5 to 7. The constituted solution may vary in color from yellow to red-orange or red.

**Storage:** Store the intact vials under refrigeration (2-8 °C).

**Stability:** Shelf-life surveillance of the intact vials is ongoing. Intact vials are stable for at least 3 years at room temperature (22-25 °C) and under refrigeration (2-8 °C). The intact vials are stable for at least one year at elevated temperature (50 °C).

Amonafide is stable in aqueous phosphate-buffered solutions over a pH range of 5.4 to 9.4 exhibiting little or no decomposition over 8 hours at 90 °C. However, at lower pH values increased rates of decomposition occur.

When constituted as directed with Sterile Water for Injection, USP, or 0.9% Chloride Injection, USP, amonafide solutions exhibit no decomposition over 14 days at room temperature or under refrigeration.

Further dilution to a concentration of 0.25 mg/mL in 0.9% Sodium Chloride Injection, USP, in glass or PVC containers results in a solution which exhibits no decomposition over 14 days of storage at room temperature or under refrigeration.

**Note:** Amonafide is very unstable in dextrose-containing solutions. Approximately 25 to 35% decomposition occurs over 24 hours at room temperature in 5% Dextrose Injection, USP, 5% Dextrose in 0.9% Sodium Chloride Injection, USP, and 5% Dextrose in 0.45% Sodium Chloride Injection, USP. The dextrose content may be catalyzing the degradation.

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

**Route of Administration:** Intravenous