

Halothane, morphine, fentanyl, alfentanil and sufentanil do not impact exposure to endogenous vasopressin.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No formal carcinogenicity or fertility studies with vasopressin have been conducted in animals. Vasopressin was found to be negative in the *in vitro* bacterial mutagenicity (Ames) test and the *in vitro* Chinese hamster ovary (CHO) cell chromosome aberration test. In mice, vasopressin has been reported to have an effect on sperm function, including motility, fertilization and embryonic development.

13.2 Animal Toxicology and/or Pharmacology

No toxicology studies were conducted with vasopressin.

14 CLINICAL STUDIES

Increases in systolic and mean blood pressure following administration of vasopressin were observed in 7 studies in septic shock and 8 studies in post-cardiotomy vasodilatory shock.

16 HOW SUPPLIED/STORAGE AND HANDLING

Vasopressin injection, USP is a clear, practically colorless solution for intravenous administration available as:

NDC 0517-1020-25: A carton of 25 single-dose vials each containing vasopressin 20 units/mL.

1 mL Vial: Storage is permitted for up to 12 months at controlled room temperature (USP) 20°C to 25°C (68°F to 77°F) within the expiry date. Once removed from refrigeration, mark the unopened vial with the revised 12-month expiration date. Do not return Vasopressin to the refrigerator after it has been stored at room temperature. Discard the product after 12 months at room temperature or at the expiry date, whichever is earlier.

Store refrigerated between 2°C and 8°C (36°F and 46°F). Do not freeze.

The storage conditions and expiration periods (for the **1 mL** vial) are summarized in Table 2.

Table 2

	Unopened Refrigerated 2°C to 8°C (36°F to 46°F)	Unopened Room Temperature 20°C to 25°C (68°F to 77°F) Do not store above 25°C (77°F)	Opened (After First Puncture)
1 mL Vial	Until manufacturer expiration date	12 months or until manufacturer expiration date, whichever is earlier	N/A

NDC 0517-1030-01: A carton of one multiple-dose vial containing vasopressin 200 units/10 mL (20 units/mL).

10 mL Vial: Storage is permitted for up to **2 months** at controlled room temperature (USP) 20°C to 25°C (68°F to 77°F) within the expiry date. Once removed from refrigeration, mark the unopened vial with the revised **2-month** expiration date. Do not return Vasopressin to the refrigerator after it has been stored at room temperature. Discard the product after **2 months** at room temperature or at the expiry date, whichever is earlier.

After initial entry into the 10 mL vial, the remaining contents must be refrigerated. Discard the refrigerated 10 mL vial after 30 days after first puncture.

Store refrigerated between 2°C and 8°C (36°F and 46°F). Do not freeze.

The storage conditions and expiration periods (for the **10 mL** vial) are summarized in Table 3.

Table 3

	Unopened Refrigerated 2°C to 8°C (36°F to 46°F)	Unopened Room Temperature 20°C to 25°C (68°F to 77°F) Do not store above 25°C (77°F)	Opened (After First Puncture)
10 mL Vial	Until manufacturer expiration date	2 months or until manufacturer expiration date, whichever is earlier	30 days

Distributed by:

 AMERICAN REGENT, INC.
SHIRLEY, NY 11967

RQ1093-D