

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 function and fertilizing ability of spermatozoa.

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 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:

Product Code	Unit of Sale	Strength	Unit of Use
930101	NDC 63323-930-01 A tray of 25 Single Dose Vials	20 Units per 1 mL	NDC 63323-930-00 1 mL Single Dose Vial
RF930101	NDC 65219-039-01 A tray of 25 Single Dose Vials	20 Units per 1 mL	NDC 65219-039-00 1 mL Single Dose Vial

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

Vials may be held up to 12 months upon removal from refrigeration to room temperature storage conditions (20°C to 25°C [68°F to 77°F], [see USP Controlled Room Temperature]), anytime within the labeled shelf life. Once removed from refrigeration, unopened vial should be marked to indicate the revised 12 month expiration date. If the manufacturer's original expiration date is shorter than the revised expiration date, then the shorter date must be used. Do not use Vasopressin injection beyond the manufacturer's expiration date stamped on the vial.

The storage conditions and expiration periods are summarized in the following table.

	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)
1 mL Vial	Until manufacturer expiration date	12 months or until manufacturer expiration date, whichever is earlier