Vasopressin Injection, USP

PRODUCT	DELIVERY SYSTEM	UNIT SIZE	UNITS / BOX	NDC#
Vasopressin Injection, USP	Single-Dose Vial	1 mL	10	0548-9701-00

	WHOLESALER ITEM NUMBERS			
NDC#	AMERISOURCE BERGEN	CARDINAL	MCKESSON	MORRIS & DICKSON
0548-9701-00	10271043	5798376	2631141	234054

For more information,
PLEASE CALL 1-800-423-4136

AMPHASTAR PHARMACEUTICALS INC.
11570 Sixth Street, Rancho Cucamonga, CA 91730
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See over for prescribing information

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08/22
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Vasopressin Injection, USP

INDICATIONS AND USAGE

Vasopressin Injection, USP is indicated to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines.

DOSAGE AND ADMINISTRATION

Preparation of Solution

Inspect parenteral drug products for particulate matter and discoloration prior to use, whenever solution and container permit.

Dilute Vasopressin Injection, USP in normal saline (0.9% sodium chloride) or 5% dextrose in water (D5W) prior to use for intravenous administration. Discard unused diluted solution after 18 hours at room temperature or 24 hours under refrigeration.

Table 1 Preparation of diluted solutions

Fluid restriction?	Final concentration	Mix	
		Vasopressin Injection, USP	Diluent
No	0.1 units/mL	2.5 mL (50 units)	500 mL
Yes	1 unit/mL	5 mL (100 units)	100 mL

Administration

In general, titrate to the lowest dose compatible with a clinically acceptable response.

The recommended starting dose is:

Post-cardiotomy shock: 0.03 units/minute

Septic Shock: 0.01 units/minute

Tritate up by 0.005 units/minute at 10- to 15-minute intervals until the target blood pressure is reached. There are limited data for doses above 0.1 units/minute for post-cardiotomy shock and 0.07 units/minute for septic shock. Adverse reactions are expected to increase with higher doses.

After target blood pressure has been maintained for 8 hours without the use of catecholamines, taper vasopressin injection by 0.005 units/minute every hour as tolerated to maintain target blood pressure.

DOSAGE FORMS AND STRENGTHS

Vasopressin Injection, USP is a clear, practically colorless solution for intravenous administration available as 20 units/mL in a single dose vial. To be used after dilution.

CONTRAINDICATIONS

Vasopressin Injection, USP 1 mL single dose vial is contraindicated in patients with known allergy or hypersensitivity to 8-L-arginine vasopressin or chlorobutanol.

WARNINGS AND PRECAUTIONS

Worsening Cardiac Function

A decrease in cardiac index may be observed with the use of Vasopressin Injection, USP.

Reversible Diabetes Insipidus

Patients may experience reversible diabetes insipidus, manifested by the development of polyuria, a dilute urine, and hypernatremia, after cessation of treatment with vasopressin. Monitor serum electrolytes, fluid status, and urine output after vasopressin discontinuation. Some patients may require readministration of vasopressin or administration of desmopressin to correct fluid and electrolyte shifts.

ADVERSE REACTIONS

The following adverse reactions associated with the use of vasopressin were identified in the literature. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to estimate their frequency reliably or to establish a causal relationship to drug exposure.

Bleeding/lymphatic system disorders: Hemorrhagic shock, decreased platelets, intractable bleeding

Cardiac disorders: Right heart failure, atrial fibrillation, bradycardia, myocardial ischemia

Gastrointestinal disorders: Mesenteric ischemia

Hepatobiliary: Increased bilirubin levels

Renal/urinary disorders: Acute renal insufficiency

Vascular disorders: Distal limb ischemia

Metabolic: Hyponatremia

Skin: Ischemic lesions

Postmarketing Experience

Reversible diabetes insipidus *[see Warnings and Precautions (5.2)]*.

OVERDOSAGE

Overdosage with Vasopressin Injection, USP can be expected to manifest as consequences of vasoconstriction of various vascular beds (peripheral, mesenteric, and coronary) and as hyponatremia. In addition, overdosage may lead less commonly to ventricular tachyarrhythmias (including Torsade de Pointes), rhabdomyolysis, and non-specific gastrointestinal symptoms.

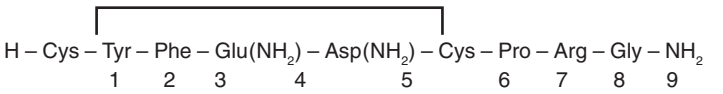
Direct effects will resolve within minutes of withdrawal of treatment.

DESCRIPTION

Vasopressin is a polypeptide hormone. Vasopressin Injection, USP is a sterile, aqueous solution of synthetic arginine vasopressin for intravenous administration.

The 1 mL solution contains vasopressin 20 units/mL, chlorobutanol, NF 0.5% as a preservative, and Water for Injection, USP adjusted with acetic acid to pH 3.4-3.6.

The chemical name of vasopressin is Cyclo (1-6) L-Cysteinyl-L-Tyrosyl-L-Phenylalanyl-L-Glutaminyl-L-Asparaginyl-L-Cysteinyl-L-Prolyl-L-Arginyl-L-Glycinamide. It is a white to
off-white amorphous powder, freely soluble in water. The structural formula is:



Molecular Formula: $C_{46}H_{65}N_{15}O_{12}S_2$ Molecular Weight: 1084.23

One mg is equivalent to 530 units.

The ganglionic blocking agent tetra-ethylammonium increases the pressor effect of vasopressin by 20% in healthy subjects *[see Drug Interactions (7.3)]*.

Halothane, morphine, fentanyl, alfentanyl and sufentanyl do not impact exposure to endogenous vasopressin.

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.

HOW SUPPLIED/STORAGE AND HANDLING

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

A carton of 10 single dose vials. Each vial contains vasopressin 1 mL at 20 units/mL.
NDC 0548-9701-00 Stock No. 9701

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], 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, USP 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)	Opened (After First Puncture)
1 mL Vial	Until manufacturer expiration date	12 months or until manufacturer expiration date, whichever is earlier	N/A

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Rev. 07/21