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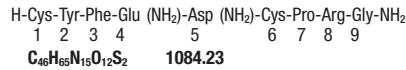
June 2009

## **Vasopressin** Injection, USP

### **Synthetic**

#### **DESCRIPTION**

Vasopressin Injection, USP is a sterile, nonpyrogenic solution of synthetic vasopressin of the posterior pituitary gland. It is substantially free from the oxytocic principle and is standardized to contain 20 pressor units/mL. The chemical name is Vasopressin, 8-L-arginine and has the following structural formula:



Each mL contains: 20 USP Vasopressin units; chlorobutanol (anhydrous) 5 mg as preservative; Water for Injection q.s. Glacial acetic acid and/or sodium hydroxide for pH adjustment (2.5 - 4.5).

#### **CLINICAL PHARMACOLOGY**

The antidiuretic action of vasopressin is ascribed to increasing reabsorption of water by the renal tubules.

Vasopressin can cause contraction of smooth muscle of the gastrointestinal tract and of all parts of the vascular bed, especially the capillaries, small arterioles and venules with less effect on the smooth musculature of the large veins. The direct effect on the contractile elements is neither antagonized by adrenergic blocking agents nor prevented by vascular denervation.

#### **INDICATIONS AND CLINICAL USE**

Vasopressin Injection, USP is indicated for prevention and treatment of postoperative abdominal distention, in abdominal roentgenography to dispel interfering gas shadows, and in diabetes insipidus.

#### **CONTRAINDICATIONS**

Anaphylaxis or hypersensitivity to the drug or its components.

#### **WARNINGS**

This drug should not be used in patients with vascular disease, especially disease of the coronary arteries, except with extreme caution. In such patients, even small doses may precipitate anginal pain, and with larger doses, the possibility of myocardial infarction should be considered.

Vasopressin may produce water intoxication. The early signs of drowsiness, listlessness, and headaches should be recognized to prevent terminal coma and convulsions.

#### **PRECAUTIONS**

Vasopressin should be used cautiously in the presence of epilepsy, migraine, asthma, heart failure or any state in which a rapid addition to extracellular water may produce hazard for an already overburdened system.

Chronic nephritis with nitrogen retention contraindicates the use of vasopressin until reasonable nitrogen blood levels have been attained.

#### **ADVERSE REACTIONS**

Local or systemic allergic reactions may occur in hypersensitive individuals. The following side effects have been reported following the administration of vasopressin: tremor, sweating, vertigo, circumoral pallor, "pounding" in head, abdominal cramps, passage of gas, nausea, vomiting, urticaria, bronchial constriction. Anaphylaxis (cardiac arrest and/or shock) have been observed shortly after injection of vasopressin.

#### **DOSAGE AND ADMINISTRATION**

Vasopressin Injection, USP may be administered intramuscularly (i.m.) or subcutaneously (s.c.).

Ten units (0.5 mL) of Vasopressin Injection will usually elicit full physiologic response in adult patients; 5 units (0.25 mL) will be adequate in many cases. Vasopressin Injection should be given i.m. at three or four hour intervals as needed. The dosage should be proportionately reduced for children. (For an additional discussion of dosage, consult the sections below.)

When determining the dose of Vasopressin Injection for a given case, the following should be kept in mind:

It is particularly desirable to give a dose not much larger than is just sufficient to elicit the desired physiologic response. Excessive doses may cause undesirable side actions – blanching of the skin, abdominal cramps, nausea – which, though not serious, may be alarming to the patient. Spontaneous recovery from such side actions occurs in a few minutes. It has been found that one or two glasses of water given at the time Vasopressin Injection is administered reduces such symptoms.

#### **Abdominal Distention**

In the average postoperative adult patient, give 5 units (0.25 mL) initially, increase to 10 units (0.5 mL) at subsequent injections if necessary. It is recommended that vasopressin be given i.m. and that injections be repeated at three or four hour intervals as required. Dosage to be reduced proportionately for children.

Vasopressin used in this manner will frequently prevent, or relieve, postoperative distention. These recommendations apply also to distention complicating pneumonia or other acute toxemias.

#### **Abdominal Roentgenography**

For the average case, two injections of 10 units (0.5 mL) each are suggested. These should be given two hours and one-half hour, respectively before films are exposed. Many roentgenologists advise giving an enema prior to the first dose of vasopressin.

#### **Diabetes Insipidus**

Vasopressin may be given by injection or administered intranasally on cotton pledgets, by nasal spray, or by dropper. The dose by injection is 5 to 10 units (0.25 to 0.5 mL) repeated two or three times daily as needed. When Vasopressin Injection is administered intranasally by spray or on pledgets, the dosage and interval between treatments must be determined for each patient.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

#### **AVAILABILITY OF DOSAGE FORMS**

C30201 Vasopressin Injection, 20 USP units/mL, 1 mL in 2 mL (partially filled) flip-top vials in packages of 25.

#### **STORAGE AND STABILITY**

Store between 15 and 30°C. Do not permit to freeze.

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