PITRESSIN- vasopressin injection
Cardinal Health

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Pitressin®
(Vasopressin Injection, USP)
SYNTHETIC

DESCRIPTION

Pitressin (Vasopressin Injection, USP) Synthetic is a sterile, aqueous solution of synthetic vasopressin (8-Arginine vasopressin) of the posterior pituitary gland. It is substantially free from the oxytocic principle and is standardized to contain 20 USP units/mL. The solution contains 0.5% Chlorobutanol (chloroform derivative) as a preservative. The acidity of the solution is adjusted with acetic acid.

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.

Following subcutaneous or intramuscular administration of vasopressin injection, the duration of antidiuretic activity is variable but effects are usually maintained for 2 to 8 hours.

The majority of a dose of vasopressin is metabolized and rapidly destroyed in the liver and kidneys. Vasopressin has a plasma half-life of about 10 to 20 minutes. Approximately 5% of a subcutaneous dose of vasopressin is excreted in urine unchanged after 4 hours.

CONTRAINDICATION

Anaphylaxis or hypersensitivity to the drug or its components.

INDICATIONS AND USAGE

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

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

General

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.

Information for Patients

Side effects such as blanching of skin, abdominal cramps, and nausea may be reduced by taking 1 or 2 glasses of water at the time of vasopressin administration. These side effects are usually not serious and probably will disappear within a few minutes.

Laboratory Tests

Electrocardiograms (ECG) and fluid and electrolyte status determinations are recommended at periodic intervals during therapy.

Drug Interactions

1) The following drugs may potentiate the antidiuretic effect of vasopressin when used concurrently: carbamazepine; chlorpropamide; clofibrate; urea; fludrocortisone; tricyclic antidepressants. 2) The following drugs may decrease the antidiuretic effect of vasopressin when used concurrently: demeclocycline; norepinephrine; lithium; heparin; alcohol. 3) Ganglionic blocking agents may produce a marked increase in sensitivity to the pressor effects of vasopressin.

Pregnancy Category C

Animal reproduction studies have not been conducted with Pitressin. It is also not known whether Pitressin can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Pitressin should be given to a pregnant woman only if clearly needed.

Labor and Delivery

Doses of vasopressin sufficient for an antidiuretic effect are not likely to produce tonic uterine contractions that could be deleterious to the fetus or threaten the continuation of the pregnancy.

Nursing Mothers

Caution should be exercised when Pitressin is administered to a nursing woman.

ADVERSE REACTIONS

Local or systemic allergic reactions may occur in hypersensitive individuals. The following side effects have been reported following the administration of vasopressin.

Body as a Whole: anaphylaxis (cardiac arrest and/or shock) has been observed shortly after injection of vasopressin.

Cardiovascular: cardiac arrest, circumoral pallor, arrhythmias, decreased cardiac output, angina, myocardial ischemia, peripheral vasoconstriction, and gangrene.

Gastrointestinal: abdominal cramps, nausea, vomiting, passage of gas.

Nervous System: tremor, vertigo, "pounding" in head.

Respiratory: bronchial constriction.

Skin and Appendages: sweating, urticaria, cutaneous gangrene.

Overdosage

Water intoxication may be treated with water restriction and temporary withdrawal of vasopressin until polyuria occurs. Severe water intoxication may require osmotic diuresis with mannitol, hypertonic dextrose, or urea alone or with furosemide.

For medical advice about adverse reactions contact your medical professional. To report SUSPECTED ADVERSE REACTIONS, contact JHP at 1-866-923-2547 or MEDWATCH at 1-800-FDA-1088 (1-800-332-1088) or http://www.fda.gov/medwatch/.

DOSAGE AND ADMINISTRATION

Pitressin may be administered subcutaneously or intramuscularly.

Ten units of Pitressin (0.5 mL) will usually elicit full physiologic response in adult patients; 5 units will be adequate in many cases. Pitressin should be given intramuscularly at 3- or 4-hour intervals as needed. The dosage should be proportionately reduced for pediatric patients. (For an additional discussion of dosage, consult the sections below.)

When determining the dose of Pitressin 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 effects—blanching of the skin, abdominal cramps, nausea—which, though not serious, may be alarming to the patient. Spontaneous recovery from such side effects occurs in a few minutes. It has been found that one or two glasses of water given at the time Pitressin is administered reduce 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 Pitressin be given intramuscularly and that injections be repeated at 3- or 4-hour intervals as required. Dosage to be reduced proportionately for pediatric patients.

Pitressin 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 each (0.5 mL) 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 Pitressin.

Diabetes Insipidus

Pitressin 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 Pitressin is administered intranasally by spray or on pledgets, the dosage and interval between treatments must be determined for each patient.

HOW SUPPLIED

Pitressin (Vasopressin Injection, USP) Synthetic is supplied in vials as follows:

NDC 42023-117-25
1 mL vial (20 USP units). Packages of 25 vials.

Store between 20° to 25°C (68° to 77°F). (See USP Controlled Room Temperature.)

Rx only.

Prescribing Information as of October 2012.

JHP Pharmaceuticals
Manufactured and Distributed by:
JHP Pharmaceuticals, LLC
Rochester, MI 48307

3000403D

Package/Label Display Panel

Pitressin

20 USP units per mL

Vasopressin Injection, USP

1 x 1 mL VIAL

PITRESSIN
20 USP units per mL
Vasopressin Injection, USP

1 x 1 mL VIAL

Synthetic

For Intramuscular or Subcutaneous Injection.

Note – Vials are oversized.

Usual Adult Dosage – Initially, 5 to 10 units (0.25 to 0.5 mL) intramuscularly or subcutaneously. May be repeated as indicated.

See product insert for full prescribing information, precautions and warnings.

Contains 0.5% chlorobutanol (chloroform derivative) as a preservative.
Acidity adjusted with acetic acid.

RX ONLY

STORAGE: Store between 20 to 25 C (68 to 77 F).
(See USP Controlled Room Temperature.)

Bulk NDC 42023-117-25

Manufactured and Distributed by:
JHP Pharmaceuticals, LLC, Rochester, MI 48307

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Repackaged by Cardinal Health
Zanesville, OH 43701
LA67230114

Cardinal Health Item # AR6723

LOT #: XXXX

EXP. DATE: 12/34

PITRESSIN

vasopressin injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:55154-5925(NDC:42023-117)
Route of Administration	SUBCUTANEOUS, INTRAMUSCULAR		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
vasopressin (UNII: Y87Y826H08) (vasopressin - UNII:Y87Y826H08)	vasopressin	20 [USP'U] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Chlorobutanol (UNII: HM4YQM8WRC)	
acetic acid (UNII: Q40Q9N063P)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55154-5925-8	1 in 1 BAG		
1		1 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		10/01/2007	

Labeler - Cardinal Health (188557102)

Establishment

Name	Address	ID/FEI	Business Operations
Cardinal Health		188557102	REPACK(55154-5925)

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