AVENACY

Desmopressin

Acetate Injection, USP

4 mcg	NDC 83634-451-01 4 mcg per mL
DESCRIPTION	Single-Dose Vial
CONCENTRATION	4 mcg per mL
CLOSURE	13 mm
UNIT OF SALE	10 Vials
BAR CODED	Yes
STORAGE	Refrigerated

40 mcg	NDC 83634-451-10 40 mcg per 10 mL
DESCRIPTION	Multi-Dose Vial
CONCENTRATION	4 mcg per mL
CLOSURE	13 mm
UNIT OF SALE	1 Vial
BAR CODED	Yes
STORAGE	Refrigerated

• AP RATED • NOT MADE WITH NATURAL RUBBER LATEX •

PLEASE SEE IMPORTANT SAFETY INFORMATION ATTACHED, INCLUDING BOXED WARNING.

VISIT WWW.AVENACY.COM/PRODUCTS/DESMOPRESSIN-ACETATE-INJECTION-USP FOR FULL PRESCRIBING INFORMATION.

ORDER THROUGH YOUR WHOLESALER:

STRENGTH	Cencora/ABC	Cardinal	McKesson	Morris Dickson
4 mcg per mL	10286576	5899885	2907475	366575
40 mcg per 10 mL	10286558	5899893	2907491	366583

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DESMOPRESSIN ACETATE Injection

INDICATIONS AND USAGE

- *Central Diabetes Insipidus*- Desmopressin Acetate Injection is indicated as antidiuretic replacement therapy in the management of central (cranial) diabetes insipidus and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.
  - o Limitations of Use- Desmopressin Acetate is ineffective and not indicated for the treatment of nephrogenic diabetes insipidus.
- *Hemophilia A*- Desmopressin Acetate Injection is indicated for patients with hemophilia A with factor VIII coagulant activity levels greater than 5% without factor VIII antibodies to:
  - o Maintain hemostasis during surgical procedures and postoperatively.
  - o Reduce bleeding with episodes of spontaneous or traumatic injuries such as hemarthroses, intramuscular hematomas, or mucosal bleeding.
- *von Willebrand's Disease (Type I)*- Desmopressin Acetate Injection is indicated for patients with mild to moderate von Willebrand's disease (Type I) with factor VIII levels greater than 5% to:
  - o Maintain hemostasis during surgical procedures and postoperatively.
  - o Reduce bleeding with episodes of spontaneous or traumatic injuries such as hemarthroses, intramuscular hematomas, or mucosal bleeding.
  - o Limitations of Use- Desmopressin Acetate is not indicated for the treatment of severe von Willebrand's disease (Type I) and when there is evidence of an abnormal molecular form of factor VIII antigen.

WARNING: HYPONATREMIA

Desmopressin Acetate can cause hyponatremia. Severe hyponatremia can be life-threatening, leading to seizures, coma, respiratory arrest, or death.

Desmopressin Acetate is contraindicated in patients at increased risk of severe hyponatremia, such as patients with excessive fluid intake, illnesses that can cause fluid or electrolyte imbalances, and in those using loop diuretics or systemic or inhaled glucocorticoids.

Ensure the serum sodium concentration is normal before starting or resuming Desmopressin Acetate. Measure serum sodium within 7 days and approximately 1 month after initiating therapy, and periodically during treatment. More frequently monitor serum sodium in patients 65 years of age and older and in patients at increased risk of hyponatremia.

If hyponatremia occurs, Desmopressin Acetate may need to be temporarily or permanently discontinued.

CONTRAINDICATIONS

Desmopressin Acetate Injection is contraindicated in patients with known hypersensitivity to desmopressin acetate or to any of the components of Desmopressin Acetate Injection.

Desmopressin Acetate Injection is contraindicated in patients with the following conditions due to an increased risk of hyponatremia:

- Moderate to severe renal impairment defined as a creatinine clearance below 50 mL/min
- Hyponatremia or a history of hyponatremia
- Known or suspected syndrome of inappropriate antidiuretic hormone (SIADH) secretion
- Polydipsia
- Concomitant use with loop diuretics
- Concomitant use with systemic or inhaled glucocorticoids
- During illnesses that can cause fluid or electrolyte imbalance, such as gastroenteritis, salt-wasting nephropathies, or systemic infection

Desmopressin Acetate Injection is contraindicated in patients with the following conditions because fluid retention increases the risk of worsening the underlying condition:

- Heart failure
- Uncontrolled hypertension

WARNINGS and PRECAUTIONS

- *Hyponatremia*- Desmopressin Acetate Injection can cause hyponatremia. Severe hyponatremia can be life-threatening if it is not promptly diagnosed and treated, leading to seizures, coma, respiratory arrest, or death.
  - o Desmopressin Acetate Injection is contraindicated in patients with hyponatremia (or a history of hyponatremia), with excessive fluid intake (e.g., polydipsia), using loop diuretics or systemic or inhaled glucocorticoids, with known or suspected SIADH, and/or illnesses that can cause fluid or electrolyte imbalances. Avoid concomitant treatments that also cause hyponatremia.
  - o Prior to starting or resuming Desmopressin Acetate Injection, ensure that the serum sodium concentration is normal. Limit fluid intake to a minimum from 1 hour before administration until 8 hours after administration. Use of Desmopressin Acetate Injection without concomitant reduction of fluid intake may lead to fluid retention and hyponatremia.
  - o Monitor the serum sodium concentration within 1 week and approximately 1 month of initiating Desmopressin Acetate Injection, and periodically thereafter. Base the frequency of serum sodium monitoring on the patient's risk of hyponatremia.
  - o Patients with conditions associated with fluid and electrolyte imbalance (i.e., cystic fibrosis, heart failure, and renal disorders), geriatric and pediatric patients, patients receiving concomitant treatments that also cause hyponatremia

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(i.e., tricyclic antidepressants, selective serotonin reuptake inhibitors, nonsteroidal anti-inflammatory drugs, chlorpromazine, opiate analgesics, carbamazepine, lamotrigine, thiazide diuretics and chlorpropamide), and patients with habitual or psychogenic polydipsia who may drink excessive amounts of water, may be at increased risk of hyponatremia.

- o If hyponatremia occurs, Desmopressin Acetate Injection may need to be temporarily or permanently discontinued and treatment for the hyponatremia instituted, depending on the clinical circumstances, including the duration and severity of the hyponatremia.

- *Hypotension and Hypertension*- Desmopressin Acetate may cause hypotension (with compensatory increase in heart rate) or hypertension. Monitor blood pressure during Desmopressin Acetate administration, particularly in patients with a history of coronary artery insufficiency and/or hypertensive cardiovascular disease.
- *Increased Risk of Thrombosis in Patients with von Willebrand's Disease Type IIB*- Use of Desmopressin Acetate in patients with Type IIB von Willebrand's disease may result in platelet aggregation, thrombocytopenia, and possibly thrombosis.
- *Hypersensitivity Reactions*- Hypersensitivity reactions including anaphylaxis have been reported with intravenous and intranasal Desmopressin Acetate, including cases of fatal anaphylaxis with intravenous Desmopressin Acetate. Desmopressin Acetate Injection is contraindicated in patients with known hypersensitivity to desmopressin acetate or to any of the components of Desmopressin Acetate Injection. It is not known whether antibodies to Desmopressin Acetate Injection are produced after repeated injections. Monitor patients for signs or symptoms of hypersensitivity reactions during administration, interrupt treatment should a reaction occur, and manage medically. Permanently discontinue for serious hypersensitivity reaction.
- *Fluid Retention*- Desmopressin Acetate Injection can cause fluid retention, which can worsen underlying conditions that are susceptible to volume status. Patients with heart failure or uncontrolled hypertension may be at increased risk. Desmopressin Acetate Injection is not recommended in patients at risk for increased intracranial pressure or those with a history of urinary retention.

  o Advise patients to limit fluid intake.

ADVERSE REACTIONS

Common adverse reactions are abdominal cramps, burning pain, erythema, facial flushing, fluid retention, headache, hypersensitivity reactions, hypertension, hyponatremia, hyponatremic seizures, hypotension, nausea, swelling, tachycardia, and thrombotic events.

OVERDOSAGE

Overdosage of Desmopressin Acetate Injection leads to prolonged duration of action with an increased risk of water retention and hyponatremia. Signs of overdose may include headaches, abdominal cramps, nausea, facial flushing, confusion, drowsiness, problems with passing urine and rapid weight gain due to fluid retention. In case of overdosage, the dosage should be reduced, frequency of administration decreased, or the drug withdrawn according to the severity of the condition, serum sodium assessed, and hyponatremia treated appropriately. There is no known specific antidote for desmopressin acetate or Desmopressin Acetate Injection 4 mcg/mL.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for DESMOPRESSIN ACETATE Injection.