

PART III: CONSUMER INFORMATION

Pr **DESMOPRESSIN SPRAY, 10 µg/spray**
(Desmopressin Acetate Nasal Solution)

This leaflet is part III of a three-part “Product Monograph” published when DESMOPRESSIN SPRAY was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about DESMOPRESSIN SPRAY. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

DESMOPRESSIN SPRAY is used to prevent or control the frequent urination, extreme thirst, and loss of water associated with *Diabetes Insipidus (water diabetes)*, following head trauma and surgery in the pituitary gland.

Diabetes Insipidus (DI) is a medical condition in which your kidneys are unable to retain water. This results in the production of large volumes of urine which in turn makes you feel dry and very thirsty.

It is important to point out that DI is **not** related to the type of diabetes most people have heard of, Diabetes Mellitus (sugar diabetes).

In DI, there is no problem with the sugar in the blood or urine.

What it does:

DESMOPRESSIN SPRAY contains desmopressin, an antidiuretic hormone. DESMOPRESSIN SPRAY reduces the amount of urine that the body makes, thereby reducing symptoms of DI such as thirst and passing a lot of urine.

When it should not be used:

Do not take DESMOPRESSIN SPRAY if any of the following conditions applies to you or your child:

- Allergic reaction to desmopressin acetate or any of the other ingredients in DESMOPRESSIN SPRAY
- Bleeding problems such as Type II B or platelet-type (pseudo) von Willebrand’s disease
- Excess fluid consumption
- Heart failure or other conditions requiring treatment with diuretics (water pills)

- Kidney problems or failure
- Hyponatremia (low blood sodium levels)
- Primary nocturnal enuresis (bedwetting)

What the medicinal ingredient is:

Desmopressin acetate.

What the nonmedicinal ingredients are:

The nonmedicinal ingredients are:

benzalkonium chloride 0.01% as a preservative, citric acid, sodium chloride, sodium phosphate dibasic and purified water

What dosage forms it comes in:

DESMOPRESSIN SPRAY (desmopressin acetate nasal solution) 10 µg/spray is available as a pre-compression metered dose spray pump. Each depression delivers 10 µg of desmopressin acetate. Available in bottles of 2.5 mL (25 sprays) and 5.0 mL (50 sprays).

WARNINGS AND PRECAUTIONS

BEFORE you use DESMOPRESSIN SPRAY talk to your doctor or pharmacist if you are:

- Breast-feeding
- Pregnant or think you might be pregnant

And/or if you have:

- hyponatremia (low blood sodium level)
- heart problems
- liver disease
- kidney problems
- bleeding problems
- fever
- cystic fibrosis
- any allergies to desmopressin acetate or any of the ingredients listed in “What the nonmedicinal ingredients are”

Before you commence treatment with this medicine, you should receive appropriate advice concerning fluid intake from your doctor. Excessive fluid intake may lead to a build up of water in the body resulting in water intoxication and hyponatremia. Talk to your doctor if you develop conditions associated with fluid and electrolyte imbalance, such as infections, gastroenteritis, diarrhea and vomiting because these patients are prone to hyponatremia.

DESMOPRESSIN SPRAY should not be given to dehydrated patients until water balance is adequately

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restored. Talk to your doctor before stopping or interrupting treatment with DESMOPRESSIN SPRAY.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with DESMOPRESSIN SPRAY include:

- Tricyclic antidepressants (amitriptyline, nortriptyline)
- Serotonin reuptake inhibitors (for example, fluoxetine or Prozac®, paroxetine or Paxil®, sertraline or Zoloft®, fluvoxamine or Luvox®, citalopram or Celexa®, venlafaxine or Effexor® XR, and risperidone or Risperdal®)
- Nonsteroidal anti-inflammatory drugs (NSAIDs such as etodolac or Ultradol®, ibuprofen or Advil® or Motrin®, naproxen or Naprosyn®; celecoxib or Celebrex®)
- Chlorpromazine
- Carbamazepine
- Diuretics (water pills)
- Loperamide or Imodium®
- Clofibrate
- Chlorpropamide
- Demeclocyclin
- Lithium
- Norepinephrine

If you are taking any of these drugs, please talk to your doctor or pharmacist before taking DESMOPRESSIN SPRAY.

PROPER USE OF THIS MEDICATION

How to Take DESMOPRESSIN SPRAY:

DESMOPRESSIN SPRAY does NOT work like other nasal sprays. **It is NOT supposed to be sniffed like cold or allergy sprays.** If it is sniffed up the nose, it will not work. The spray ONLY works when it is absorbed inside the nose.

Getting ready to use DESMOPRESSIN SPRAY:

Gently blow the nose. If the nose is blocked because of a cold or allergies, DESMOPRESSIN SPRAY may not work as well.

Using Your DESMOPRESSIN SPRAY:

1. Do NOT shake the bottle.
2. Remove protective cap.

3. **The spray pump must be primed prior to the first use.**

To prime pump, press down 4 times.

4. Once primed, the spray pump delivers 10 micrograms of medication each time it is pressed.
To administer one 10-microgram dose, place the spray nozzle in nostril and press the spray pump once. If a higher dose has been prescribed, spray half the dose in each nostril. The spray pump cannot be used for doses less than 10 micrograms or doses other than multiples of 10 micrograms.
5. Replace the protective cap on bottle after use. The pump will stay primed for up to one week. If the product has not been used for a period of one week, re-prime the pump by pressing once.

Using DESMOPRESSIN SPRAY for your child:

DESMOPRESSIN SPRAY should only be used in children who require a dose of 10 µg DESMOPRESSIN SPRAY taken 1, 2 or 3 times daily.

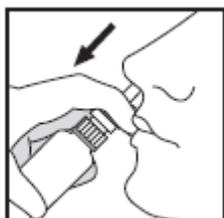
Ask your child to gently blow his/her nose. If the nose is blocked because of a cold or allergies, DESMOPRESSIN SPRAY may not work as well.

1. Do NOT shake the bottle.
2. Remove protective cap.
3. The spray pump must be primed prior to the first use. To prime pump, press down 4 times.
4. Once primed, the spray pump delivers 10 micrograms of medication each time it is pressed. To ensure dosing accuracy, tilt bottle so that dip tube inside the bottle draws from the deepest portion of the medication.
5. Always keep the bottle upright so the tube stays in the liquid and no air gets inside the tube. If an air bubble forms, the right amount of spray will not come out.

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6. Tilt the child's head back a little bit and insert the nozzle into one nostril. Ask the child to take a deep breath in and hold his/her breath only while you spray DESMOPRESSIN SPRAY into the nostril. For each spray, press down firmly on the white collar using your index and middle fingers. Support the base of the bottle with your thumb.



7. Remove the nozzle from the child's nostril.
8. Have your child place one finger on the outside of the nostril you just sprayed.
9. Slowly count to 10 out loud. As you count, the child should hold the nostril closed so the spray will not drip out.
10. When you reach 10, the child can release the finger and breathe normally.
11. Replace the protective cap on bottle after use. The pump will stay primed for up to one week. If the product has not been used for a period of one week, re-prime the pump by pressing once.

Usual Dose

Take the medication only as directed by your doctor.

The doctor will prescribe the dose most suitable for you or your child. The most commonly used doses are:

Children (3 months to 12 years)

5–30 µg daily given as a single dose or divided into two or three doses.

Adults:

10–40 µg daily given as a single evening dose or divided into two or three doses.

Overdose:

If you or your child take too much of the medication, you should immediately contact your doctor and/or the emergency room of the nearest hospital and the local poison center. Symptoms of overdose may include headache, nausea, vomiting, abdominal cramps, facial flushing and weight gain due to water retention and, in severe cases, convulsions.

Missed dose:

If you miss a dose of DESMOPRESSIN SPRAY, take the missed dose as soon as possible. Then go back to your regular dosing schedule. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medicines, side effects may be experienced. With DESMOPRESSIN SPRAY, these may include:

Common Side Effects

Headache, nausea, mild abdominal pain, cramps or discomfort, stuffy nose, nasal irritation, facial flushing and nose bleed.

Uncommon Side Effects

Dizziness, feeling cold, wheezing, rash, swelling in the face and hands, constipation, anorexia (obsession with thinness generally sought through self-starvation), increased appetite (excessive desire for food), conjunctivitis (pink eye or red eye) and an aftertaste in the mouth.

Rare Side Effects

Emotional problems in children and allergic skin reactions.

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These have occurred usually when the medication is being adjusted. Once you are taking the right amount of medicine for your condition, these side effects will usually go away. Tell your doctor about any side effects you experience.

Excessive fluid intake may lead to a build up of water which dilutes the salt in the body in severe cases. This can become a serious problem and may lead to convulsions. Early symptoms may include an unusually bad or prolonged headache, confusion, unexplained weight gain, nausea and vomiting. If you experience one or more of these symptoms, stop taking this medicine. Tell your doctor immediately or go to the nearest emergency hospital.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare	hyponatremia (low blood sodium level)		*	*
Very Rare	allergic reaction		*	*

This is not a complete list of side effects. For any unexpected effects while taking DESMOPRESSIN SPRAY, contact your doctor or pharmacist.

HOW TO STORE IT

DESMOPRESSIN SPRAY should be stored at room temperature, 15-30° C (59-86° F).

Protect from light. Do not freeze.

IMPORTANT: Always keep the bottle upright and store in an upright position.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health product to the Canada Vigilance Program by one of the following 3 ways:

- **Report online at**
www.healthcanada.gc.ca/medeffect
- **Call toll-free to 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789, or**
 - **Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, ON K1A 0K9**

Postage paid labels, Canada Vigilance Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting the sponsor, AA Pharma Inc. at:

1-877-998-9097

This leaflet was prepared by AA Pharma Inc.

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