

Important safety information about NOCTIVA

WARNING: HYPONATREMIA

See full prescribing information for complete boxed warning.

- **NOCTIVA can cause hyponatremia, which is a condition that occurs when you do not have enough sodium in your blood.**
- **Your doctor should monitor the sodium levels in your blood before you start and while you are using NOCTIVA. Mild cases of hyponatremia may not have any symptoms, but signs can include nausea, vomiting, fatigue, dizziness, headache, confusion, muscle cramps, feeling restless, and in severe cases, seizures and coma. It may be life-threatening if severe.**
- **Some people should not take NOCTIVA because of a higher risk of severe hyponatremia. You should not take NOCTIVA if you have a lot of fluid intake, have an illness that can cause fluid or electrolyte imbalances, or use loop diuretics (water pills like bumetanide or ethacrynic acid) or systemic or inhaled glucocorticoids (steroids like cortisone or prednisone).**
- **You may need to temporarily or permanently stop taking NOCTIVA if you get hyponatremia.**

What is NOCTIVA used for?

NOCTIVA is a prescription medicine nasal (nose) spray used in adults who wake up two or more times during the night to urinate due to a condition called nocturnal polyuria. Nocturnal polyuria is a condition where your body makes too much urine at night. There are other conditions that could cause you to wake up during the night to urinate. NOCTIVA is only approved for the treatment of nocturnal polyuria. Your doctor should have you measure your urine and the times that you urinate for 24 hours to determine if you have nocturnal polyuria if you have not already done this.

NOCTIVA is not intended for use in children. It has not been studied in adults less than 50 years old, so it is unknown whether NOCTIVA is safe or effective in people below this age.

Who should not take NOCTIVA?

You should not take NOCTIVA if you:

- have or have had low salt levels in your blood
- are thirsty much of the time and drink large amounts of fluids (polydipsia)
- wet the bed while sleeping at night
- are taking a type of water-pill called a loop-diuretic
- are taking a glucocorticoid (steroid) medicine, including an inhaled glucocorticoid (steroid) medicine
- have moderate to severe kidney problems
- have or may have a condition called syndrome of inappropriate antidiuretic hormone (SIADH) secretion
- have an illness that can cause you to have low levels of fluid or electrolytes in your blood, such as vomiting, diarrhea, an infection, or a kidney problem that causes you to lose too much salt
- have symptoms from a heart problem called congestive heart failure
- have high blood pressure that is not controlled

Ask your doctor if you are not sure you have any of these conditions or take any of the types of medicines listed.

What is the most important information you should know about NOCTIVA?

NOCTIVA can cause hyponatremia (low levels of sodium in the blood). Severe cases can lead to seizures, coma, or death. It can cause fluid retention (water weight gain), which can be a particular problem for people with congestive heart failure or uncontrolled high blood pressure.

Call your doctor if you have any of the following symptoms of low salt levels in your blood:

- headache
- nausea or vomiting
- drowsiness
- dizziness
- muscle cramps
- feeling restless
- fatigue
- change in your mental condition, such as confusion, or decreased awareness or alertness

Low salt levels in the blood happen more often in people treated with NOCTIVA who are 65 years old or older than in people treated with NOCTIVA who are younger than 65 years old. Your doctor should check the salt levels in your blood before you start or re-start taking NOCTIVA, during treatment with NOCTIVA, and before increasing your dose.

Ask your doctor if you should temporarily discontinue NOCTIVA if you have allergies or a cold that makes your nose runny or stuffed up, as having such symptoms could affect how your body absorbs the medicine in NOCTIVA.

What should you tell your health care provider?

Before using NOCTIVA, tell your health care provider about all of your medical conditions, including if you:

- have vomiting, diarrhea, fever, or infection
- have kidney or heart problems
- have diabetes mellitus
- have had a head injury
- have a heart problem called congestive heart failure
- have a history of not being able to empty your bladder all of the way (urinary retention)
- have any nose problems, such as blockage, stuffy nose, runny nose, or drainage
- are pregnant or plan to become pregnant. It is not known if NOCTIVA can harm your unborn baby.
- Are breastfeeding or plan to breastfeed. Desmopressin, an ingredient in NOCTIVA, passes into breast milk. Talk to your doctor about the best way to feed your baby if you use NOCTIVA.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using NOCTIVA with certain other medicines may cause serious side effects. Do not start taking any new medicines until you talk to your doctor.

Especially tell your doctor if you take a:

- water pill (diuretic)
- glucocorticoid (steroid) medicine, including an inhaled glucocorticoid (steroid) medicine
 - Your doctor should stop your treatment with NOCTIVA for a period of time while you are taking and after you stop taking an oral or inhaled glucocorticoid (steroid) medicine.
- medicine used to treat depression called a tricyclic antidepressant or selective serotonin reuptake inhibitor (SSRI)
- medicine used to treat mood disorders, such as schizophrenia or bipolar disorder called chlorpromazine
- medicine used to treat seizures, nerve pain, or bipolar disorder called carbamazepine
- non-steroidal anti-inflammatory medicine (NSAID)
- medicine that you use in your nose

There have not been any studies done to see if other medicines might interact with NOCTIVA. Ask your doctor or pharmacist if you are not sure if your medicine is one of the types listed above, or if you are unsure whether any of the medicines you already take might put you at increased risk of side effects.

How should you take NOCTIVA?

You should use NOCTIVA exactly as instructed by your health care professional. Your doctor has prescribed the strength that is best for you, and you should not use more than 1 spray of the prescribed dose at a time, even if you missed a prior dose.

What are the side effects of NOCTIVA?

NOCTIVA may cause serious side effects, including hyponatremia, which may lead to serious or life-threatening conditions, including seizure, coma, trouble breathing, or death if not treated early. NOCTIVA may also cause your body to hold too much water (fluid retention).

The most common side effects of NOCTIVA include:

- nose discomfort
- pain or swelling (inflammation) in your nose or throat
- stuffy nose
- sneezing
- high blood pressure
- back pain
- nosebleed
- inflammation of the lining of the bronchial tubes that carry air to and from your lungs that causes a cough (bronchitis)
- dizziness

These are not all of the possible side effects of NOCTIVA. You are encouraged to call your doctor for medical advice about side effects, and you can also report them to the FDA.

To report SUSPECTED SIDE EFFECTS, contact Avadel at 1-877-638-4579 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please be aware that this is not a complete listing of all safety information associated with NOCTIVA. For the full Prescribing Information, written for health care providers, visit www.noctiva.com.

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