If you wake up to urinate 2 or more times a night, ask your doctor about NOCTIVA

IMPORTANT SAFETY INFORMATION

WARNING: HYponatREMIA

See full prescribing information for complete boxed warning.

• NOCTIVA™ (desmopressin acetate) Nasal Spray 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.

Please see additional Important Safety Information throughout and enclosed full Prescribing Information.
Why do I wake up at night to urinate?

If you wake up 2 or more times a night to urinate, you may have nocturia. It’s very common and tends to happen more as people age. But nocturia isn’t a normal part of aging, and it might require treatment.

Over time, waking up multiple times a night could have an impact on your life. Here are a few examples:

Daytime tiredness
A person who wakes up a lot to urinate may not be able to function as well during the day.

Damaged relationships
When a person with nocturia wakes up, it’s not only disruptive for their sleep, but also for their partner’s.

Lost productivity
Nocturia can leave a person feeling groggy, and it’s been shown to make it hard to be productive and feel healthy.

Sometimes, drinking less fluid before bed helps. When it doesn’t, medicine may be necessary.

Treating nocturia

If you’ve been diagnosed with benign prostatic hyperplasia (BPH) or overactive bladder (OAB), your doctor may already have prescribed medicine.

But those medicines work in the bladder and prostate and, in most cases, a condition called nocturnal polyuria (your kidneys making too much urine at night) is the real reason you wake up.

In a clinical study, nocturnal polyuria was the cause of nocturia in 8 out of every 10 cases.

If your nocturia is caused by nocturnal polyuria, it’s important to find a medicine that targets the source of the problem, which is your kidneys producing too much urine at night.

Your doctor can tell you if your nocturia is caused by nocturnal polyuria. Be sure to ask them about why you wake up to urinate.
What is NOCTIVA?

NOCTIVA™ (desmopressin acetate) Nasal Spray is the first and only medicine approved by the FDA to treat nocturia due to nocturnal polyuria.

NOCTIVA helps reduce the amount of urine your kidneys produce at night. It’s available in 2 doses. Your doctor will decide which is right for you.

How can NOCTIVA help?

- NOCTIVA works in the kidneys, the source of the problem.
- NOCTIVA could help reduce the number of times you wake up to urinate.
- NOCTIVA could help reduce the amount of urine you produce at night.
- NOCTIVA is a nasal spray that you use once a night.

IMPORTANT SAFETY INFORMATION (continued)

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.

Please see additional Important Safety Information throughout and enclosed full Prescribing Information.
Taking NOCTIVA

NOCTIVA™ (desmopressin acetate) Nasal Spray is available in 2 doses: 0.83 mcg and 1.66 mcg. Your doctor will decide which dose is right for you.

3 steps:

1. Before you use NOCTIVA for the first time, pump the nasal applicator 5 times away from your face to prime the bottle.

2. Take ONE spray in ONE nostril.

3. Around 30 minutes before bed.

If you haven’t used NOCTIVA for more than 3 days, reprime it by pumping 2 times away from your face.

After opening, NOCTIVA can be stored at room temperature for up to 60 days, so you can keep it in a convenient location, like your nightstand.

While taking NOCTIVA, it’s a good idea to drink less fluids before you go to bed. Ask your doctor about other things you can do to improve your experience.

Important

If you miss a dose, do not double the dose at the next use. If your doctor increases your dose, you’ll need a new prescription. 2 sprays of the 0.83 mcg dose do not equal 1 spray of the 1.66 mcg dose.

IMPORTANT SAFETY INFORMATION (continued)

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.
Does NOCTIVA have side effects?

NOCTIVA™ (desmopressin acetate) Nasal Spray can cause side effects.

Low levels of salt (sodium) in your blood (hyponatremia) can happen with NOCTIVA. Low salt levels happen more often in people who are treated with NOCTIVA and are 65 years old or older than in people treated with NOCTIVA who are younger than 65 years old.

If you develop very low salt levels in your blood, this may lead to serious or life-threatening side effects, including seizure, coma, trouble breathing, or death if not treated early.

IMPORTANT SAFETY INFORMATION (continued)

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

IMPORTANT SAFETY INFORMATION (continued)

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.
After your doctor prescribes NOCTIVA

Avadel is committed to helping you access the treatment you need. That's why we offer 2 programs that can help lower the cost of your prescription.

If you have private insurance:

Before visiting the pharmacy, make sure you have a NOCTIVA™ (desmopressin acetate) Nasal Spray co-pay card, which will ensure you never pay more than $40 for your prescription.*

1. At your doctor's office
2. Online at www.GetNOCTIVA.com
3. By texting NOCTIVA to 46822

NoctivaCare+ Program

If you have Medicare Part D coverage, your insurance doesn’t cover NOCTIVA, or you don’t have insurance:

You may still be eligible for savings through the NOCTIVA Care+ Program. Ask your doctor about the program at your next visit.

For more information on savings programs, please visit www.GetNOCTIVA.com.

*Terms and conditions apply. You must be 18 years or older and have commercial or private insurance. Offer valid only within the United States. Offer is not valid if you are uninsured or paying cash for your prescription. Offer is not valid if you are enrolled in a federal or state healthcare program (including Medicare, Medicaid, TRICARE, or any state medical or pharmaceutical assistance program). If you have any questions, please contact customer support at 1-877-531-5028. This card is not insurance. The parties reserve the right to amend or end this program at any time without notice.

Please see additional Important Safety Information throughout and enclosed full Prescribing Information.
Important Safety Information about NOCTIVA (continued)

IMPORTANT SAFETY INFORMATION (continued)

What should you tell your health care provider?

Before using NOCTIVA™ (desmopressin acetate) Nasal Spray, 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.GetNOCTIVA.com.
NOTES

Use this space to write down anything you think is important. Notes about how often you wake up, how you feel during the day, or any other concerns you have could help your doctor make a more informed decision about your treatment.
If you wake up 2 or more times a night to urinate, discuss NOCTIVA with your doctor

The only FDA-approved treatment for nocturia due to nocturnal polyuria

Visit www.GetNOCTIVA.com to learn more.

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- have or may have a condition called syndrome of inappropriate antidiuretic hormone (SIADH) secretion
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- have symptoms from a heart problem called congestive heart failure
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