

MEDICATION GUIDE
NOCTIVA™ (nok-tee-va)
(desmopressin acetate) nasal spray
0.83 mcg/0.1 mL and 1.66 mcg/0.1 mL

Important: NOCTIVA is for use in your nose (intranasal) only.

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

NOCTIVA may cause serious side effects, including:

- **Low levels of salt (sodium) in your blood (hyponatremia) can happen with NOCTIVA.** 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.

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

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

Low salt levels in the blood 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.

Your doctor should check the salt levels in your blood before you start taking NOCTIVA, during treatment with NOCTIVA, before increasing your dose, and before you restart taking NOCTIVA if your treatment with NOCTIVA was stopped for a period of time.

To help decrease your risk of developing low levels of sodium in your blood:

- Limit the amount of fluids you drink in the evening and nighttime.
- Stop taking NOCTIVA and tell your doctor right away if you have a stomach or intestinal virus with vomiting or diarrhea or if you have an infection or fever.
- Stop taking NOCTIVA and tell your doctor right away if you develop any nose problems, such as a blockage, stuffy nose, runny nose, or drainage.

Your doctor may stop your treatment with NOCTIVA for a period of time or stop your treatment completely if you have low levels of salt in your blood during treatment with NOCTIVA.

What is NOCTIVA?

NOCTIVA is a prescription medicine used in adults who wake up 2 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 for use in children who wet the bed while sleeping at night.

NOCTIVA has not been studied in people under 50 years of age.

Do not use 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 medicines listed.

Before using NOCTIVA, tell your doctor 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 a 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

Ask your doctor or pharmacist if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

How should I use NOCTIVA?

- See the **Instructions for Use** that come with NOCTIVA for information about the right way to use NOCTIVA.
- Use NOCTIVA exactly as your doctor tells you to use it.
- NOCTIVA comes in 2 strengths. Your doctor has prescribed the strength that is best for you. If your dose of NOCTIVA is changed from 0.83 mcg/0.1 mL to 1.66 mcg/0.1 mL your doctor will give you a prescription for NOCTIVA 1.66 mcg/0.1 mL. You should not use 2 sprays of NOCTIVA 0.83 mcg/0.1 mL instead of 1 spray of NOCTIVA 1.66 mcg/0.1 mL.
- Use 1 spray of NOCTIVA in your left **or** right nostril 1 time each night, about 30 minutes before you go to bed.
- If you take too much NOCTIVA, stop taking NOCTIVA and call your doctor or get medical help right away.
- If you miss a dose of NOCTIVA, take the next dose at your regular time. Do not take 2 doses at the same time to make up for a missed dose.

What should I avoid while taking NOCTIVA?

Do not drink large amounts of fluids close to bedtime during treatment with NOCTIVA.

What are the possible side effects of NOCTIVA?

NOCTIVA can cause serious side effects.

- See “**What is the most important information I should know about NOCTIVA?**”

- **Fluid retention.** Your body may hold too much fluid (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 the possible side effects of NOCTIVA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NOCTIVA?

- **Before opening**, store NOCTIVA upright in a refrigerator between 36°F to 46°F (2°C to 8°C).
- **After opening**, store NOCTIVA upright at room temperature between 68°F to 77°F (20°C to 25°C).
- Throw away (discard) NOCTIVA 60 days after opening. Write the date the bottle is opened on the bottle label.

Keep NOCTIVA and all medicines out of the reach of children.

General information about the safe and effective use of NOCTIVA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NOCTIVA for a condition for which it was not prescribed. Do not give NOCTIVA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your doctor or pharmacist for information about NOCTIVA that is written for health professionals.

What are the ingredients in NOCTIVA?

Active ingredient: desmopressin acetate

Inactive ingredients: cyclopentadecanolide, cottonseed oil, sorbitan monolaurate, polysorbate 20, citric acid anhydrous, sodium citrate dihydrate, and water for injection

Manufactured for Avadel Specialty Pharmaceuticals, LLC, Chesterfield, MO 63005.

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Made in the USA

For more information, call 1-877-638-4579.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Approved: 03/2017

Instructions for Use
NOCTIVA™ (nok-tee-va)
(desmopressin acetate) nasal spray
0.83 mcg/0.1 mL and 1.66 mcg/0.1 mL

Read this Instructions for Use before you start using NOCTIVA and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

Important information:

- NOCTIVA is for use in your nose only.
- You will need to **prime your bottle of NOCTIVA before using it for the first time**. See “**Before your first use, follow these instructions to prime your bottle of NOCTIVA**”.
- **If you do not use NOCTIVA for more than 3 days**, you will need to **re-prime the bottle of NOCTIVA** before you start using it again. See “**Re-priming NOCTIVA**”.

Parts of your NOCTIVA nasal spray (See Figure A).

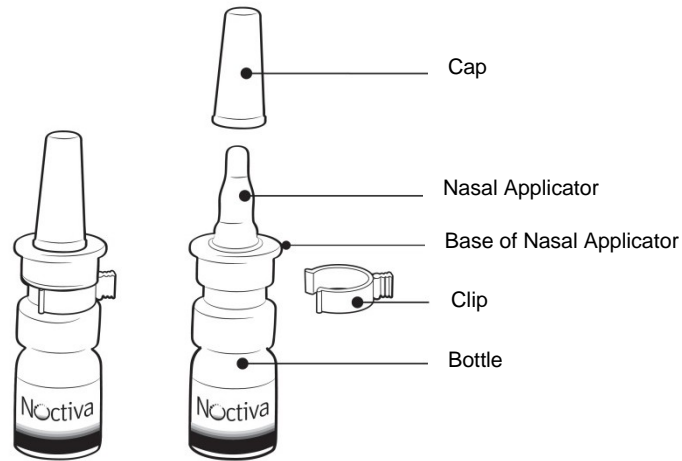


Figure A

Before your first use, follow these instructions to prime your bottle of NOCTIVA.

Prime your bottle of NOCTIVA before using it for the first time.

Do not shake the bottle.

Step 1. Pull the cap off and set it aside (See Figure B).

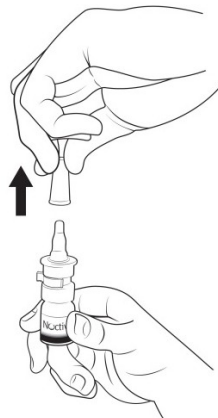


Figure B

Step 2. Remove and throw away (discard) the clip (**See Figure C**).



Figure C

Step 3. Hold the bottle upright and away from your face.
Place 1 finger on each side of the base of the nasal applicator and your thumb underneath the bottle (**See Figure D**).

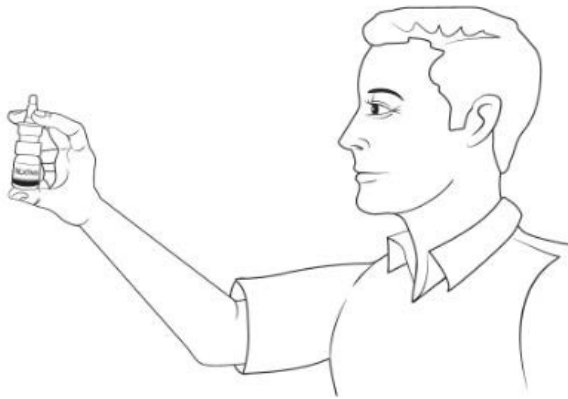


Figure D

Step 4. Completely press (pump) the nasal applicator **5 times** by squeezing your fingers and thumb together (**See Figure E**).

Keep nasal applicator pointed away from your face.

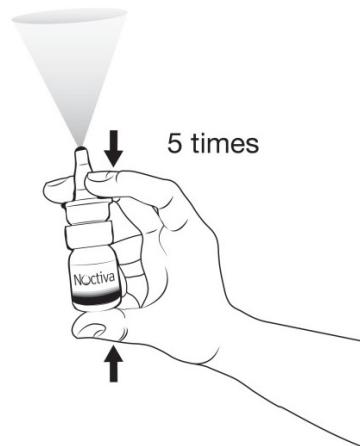


Figure E

Your NOCTIVA is now ready to use.

Using NOCTIVA

Use only 1 spray of NOCTIVA in 1 nostril each night about 30 minutes before going to bed.

Step 1. Blow your nose to clear your nostrils (See Figure F).



Figure F

Step 2. Hold the bottle upright (See Figure G).

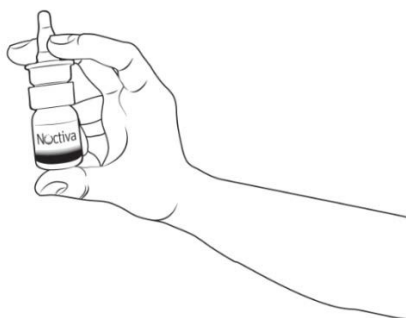


Figure G

Step 3. Tilt your head back slightly (See Figure H).



Figure H

Nasal applicator must be in an upright position to deliver the correct dose.
Do not lie down or tilt your head too far back while giving your dose of NOCTIVA.

Step 4. Insert the nasal applicator into your left **or** right nostril. Keep the nasal applicator upright. Close your open nostril with a finger from your empty hand (**See Figure I**).



Figure I

Step 5. Breathe in (inhale) gently while you pump the nasal applicator **1 time** (**See Figure J**).

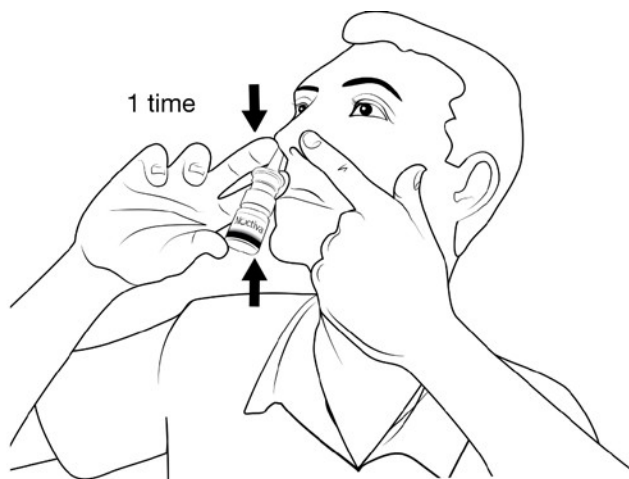


Figure J

Avoid spraying in your eyes.

Gently breathe in through your nose and out through your mouth several times.

Step 6. Wipe the nasal applicator with a clean tissue (**See Figure K**).



Figure K

Step 7. Replace the cap on the bottle (**See Figure L**).

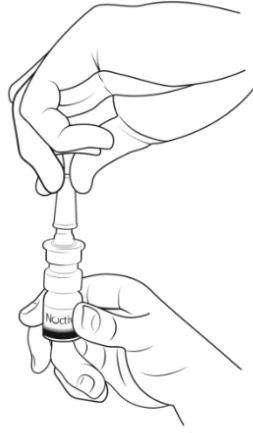


Figure L

Re-priming NOCTIVA

If you do not use NOCTIVA for more than 3 days, you will need to re-prime the bottle before you start using it again.

If you miss a dose, take the next dose at your regular time. Do not take 2 doses at the same time.

To re-prime your bottle of NOCTIVA, hold the bottle upright and away from your face. Completely press (pump) the nasal applicator 2 times. Your NOCTIVA is now ready to use.

Storage:

- **Before opening**, store NOCTIVA upright in a refrigerator between 36°F to 46°F (2°C to 8°C).
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- Throw away (discard) NOCTIVA 60 days after opening. Write the date the bottle is opened on the bottle label.

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Manufactured for: Avadel Specialty Pharmaceuticals, LLC
Chesterfield, MO 63005
Made in the USA
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