MEDICATION GUIDE NOCDURNA[®] (knock-DUHR-nah)

(desmopressin acetate) sublingual tablets

What is the most important information I should know about NOCDURNA? NOCDURNA may cause serious side effects, including:

 Low levels of salt (sodium) in your blood (hyponatremia). Low levels of salt in your blood is a serious side effect of NOCDURNA that may be life threatening, causing seizures, coma, trouble breathing or death, if not treated early.
 Stop taking NOCDURNA and call your healthcare provider if you have any of the following symptoms of low salt levels in your blood:

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headache

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- feeling restless
- drowsiness
- o muscle cramps
- nausea or o tiredness (fatigue) o dizziness vomiting
- change in your mental condition such as hallucinations, confusion, decreased awareness or alertness
- You **should not** take NOCDURNA if you are at risk for very low salt levels in your blood, for example, if you drink a lot of fluid, have illnesses that can cause you to have fluid or body salt (electrolyte) imbalances, if you take a certain type of "water-pill" called a loop diuretic or take glucocorticoids including inhaled steroids.
- Tell your healthcare provider if you have **a fever**, **infection**, **or diarrhea** while taking NOCDURNA as these can cause you to have fluid or body salt (electrolyte) imbalance. Your healthcare provider may tell you **not to take** NOCDURNA while you have these symptoms.
- Your healthcare provider should check your blood salt levels:
 - o before you start or restart taking NOCDURNA.
 - within the first week after you start NOCDURNA.
 - 1 month after you start NOCDURNA.
 - every so often as told to you by your healthcare provider, with testing more often if you are already at risk for low salt levels, for example if you are 65 years or older or take certain medicines that increase your risk of low salt levels.

See "What are the possible side effects of NOCDURNA?" for more information about side effects.

What is NOCDURNA?

NOCDURNA is a prescription medicine used in adults who wake up at least 2 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. NOCDURNA 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.

It is not known if NOCDURNA is safe and effective in children.

Do not take NOCDURNA if you:

- have or have had low sodium levels in your blood.
- are thirsty much of the time and drink large amounts of fluids (polydipsia).
- 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 or severe kidney disease.
- 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 have low levels of salt.
- have a heart condition called heart failure.
- have high blood pressure that is not controlled.
- are allergic to any ingredient in NOCDURNA tablets (see a complete list of ingredients at the end of this Medication Guide).

Talk to your healthcare provider before you take NOCDURNA if you have any of these conditions or take any of these medicines.

Before taking NOCDURNA, tell your healthcare provider about all of your medical conditions, including if you:

- are at risk for low salt levels in your blood.
- currently have vomiting, diarrhea, fever or an infection.
- have any heart or kidney problems.
- have high blood pressure.
- have increased pressure in your brain (increased intracranial pressure).
- have a history of not being able to empty your bladder all the way (urinary retention).
- are pregnant or planning to become pregnant. It is not known if NOCDURNA can harm your unborn baby. NOCDURNA is not recommended to treat normal symptoms of pregnancy that cause pregnant women to urinate often at night.
- are breastfeeding or plan to breastfeed. Desmopressin, an ingredient in NOCDURNA, passes into breastmilk. Talk to your healthcare provider about the best way to feed your baby if you take NOCDURNA.

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

Especially tell your healthcare provider if you take a:

- water pill (diuretic).
- glucocorticoid (steroid) medicine, including an inhaled glucocorticoid (steroid) medicine.
- your doctor should stop your treatment with NOCDURNA 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).

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. Tell your healthcare provider if you have fever, infection, or diarrhea while taking NOCDURNA as these can cause you to have fluid or body salt (electrolyte) imbalance. Your healthcare provider may tell you not to take NOCDURNA while you have these symptoms.

How should I take NOCDURNA?

- You should take NOCDURNA 1 time each day, 1 hour before bedtime without water.
- When you are ready to take your dose of NOCDURNA:
 - Place the tablet under your tongue 1 hour before bedtime. Leave the tablet under your tongue until it dissolves.
 - Empty your bladder just before bedtime.
- While taking NOCDURNA, you should **limit the amount of water or liquids** you drink from **1 hour before** taking NOCDURNA and until **8 hours after**. You may have serious side effects if you drink too much liquid.
- You should avoid drinks containing caffeine and alcohol before bedtime as this can cause your body to make more urine.
- Do not take more NOCDURNA than prescribed for you. If you take too much NOCDURNA, call your healthcare provider right away or get emergency treatment.

What are the possible side effects of NOCDURNA?

NOCDURNA may cause serious side effects, including:

• See "What is the most important information I should know about NOCDURNA?"

The most common side effects of NOCDURNA include:

dry mouth
 Iow levels of salt in blood (hyponatremia)
 dizziness
These are not all of the possible side effects of NOCDURNA.

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 NOCDURNA?

Store NOCDURNA at room temperature between 68° to 77°F (20° to 25°C).

Keep NOCDURNA in its blister pack until it is time to take it, in order to protect it from moisture and light.

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

General information about the safe and effective use of NOCDURNA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. **Do not use NOCDURNA** for a condition for which it was not prescribed.

Do not give NOCDURNA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about NOCDURNA that is written for health professionals.

What are the ingredients in NOCDURNA? Active ingredient: desmopressin acetate Inactive ingredients: gelatin, NF (fish source), mannitol, anhydrous citric acid

Manufactured for Antares Pharma, Inc. Ewing, NJ 08628 Origin Sweden

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For more information, go to www.NOCDURNA.com or call 609-359-3020.

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

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