NOCDURNA®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking NOCDURNA?

NOCDURNA contains the active ingredient desmopressin (as desmopressin acetate), which is a synthetic version of vasopressin, a naturally occurring substance produced in the brain. It is used to treat adults who need to get up to urinate at night (nocturia) at least two or more times, regardless of lifestyle changes.

For more information, see Section 1. Why am I taking NOCDURNA? in the full CMI.

2. What should I know before I take NOCDURNA?

Do not take if you have ever had an allergic reaction to desmopressin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I take NOCDURNA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NOCDURNA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take NOCDURNA?

- NOCDURNA is placed under the tongue where it dissolves without the need for water.
- Women: 25 micrograms daily, one hour before bedtime.
- Men: 50 micrograms daily, one hour before bedtime.

More instructions can be found in Section 4. How do I take NOCDURNA? in the full CMI.

5. What should I know while taking NOCDURNA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking NOCDURNA. • If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
Things you should not do	• Do not take NOCDURNA to treat any other complaints unless your doctor tells you to do so. • Do not stop taking your medicine or lower the dosage without checking with your doctor. • If you stop taking it suddenly, your condition may worsen.
Driving or using machines	• This medicine is not expected to affect your ability to drive a car or operate machinery.
Looking after your medicine	• Keep NOCDURNA sublingual wafers in their original container in order to protect from moisture and light, until it is time to take them. • Store it in a cool dry place, where the temperature stays below 25°C, away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while taking NOCDURNA? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

Tell your doctor if you experience any side effects, such as dry mouth, including headache, stomach pain, nausea or vomiting, rapid weight gain, confusion or drowsiness. These are signs and symptoms of hyponatraemia (low sodium levels in the blood), a serious possible side effect of NOCDURNA. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

NOCDURNA®

Active ingredient: *desmopressin (as desmopressin acetate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking NOCDURNA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking NOCDURNA.**

Where to find information in this leaflet:

1. Why am I taking NOCDURNA?

NOCDURNA contains the active ingredient desmopressin (as desmopressin acetate). Desmopressin is a synthetic version of vasopressin, a naturally occurring substance produced in the brain.

Like vasopressin, NOCDURNA works in the kidney as an antidiuretic, which reduces the amount of urine that is produced.

NOCDURNA is used to treat adults who need to get up to urinate at night (nocturia) at least two or more times, regardless of lifestyle changes (e.g. before bedtime drink only enough to satisfy thirst; and avoid alcohol and caffeine-containing beverages).

2. What should I know before I take NOCDURNA?

Before NOCDURNA treatment is started, lifestyle changes which may contribute to the production of excess urine at night should be considered.

Discuss with your doctor what lifestyle changes may be appropriate for you to make (e.g. before bedtime drink only enough to satisfy thirst; and avoid alcohol and caffeine-containing beverages).

NOCDURNA can cause low sodium levels (hyponatraemia) due to excessive fluid build-up in the body. It is important that your doctor checks your sodium levels before you start taking NOCDURNA.

Warnings

Do not take NOCDURNA if:

- you are allergic to desmopressin, or any of the ingredients listed at the end of this leaflet
- suffer from polydipsia (excessive thirst and increased fluid intake) or psychogenic polydipsia (psychologically caused increased thirst and increased fluid intake)
- where you are in the habit of drinking large amounts of fluid
- have cardiac insufficiency (heart failure in which the heart is not able to pump enough blood throughout the body resulting in shortness of breath, swelling of the feet or legs due to fluid build-up)
- have any disease requiring treatment with diuretics (water or fluid tablets)
- have moderately or severely reduced kidney function (kidney disease where little or no urine is passed)
- have or have had hyponatraemia (low sodium level in the blood)
- have cognitive impairment (e.g. diagnosed dementia)
- have or have had or are at risk of having SIADH (hormone secretion disorder where there is an overproduction of a hormone causing fluid retention, resulting in weakness, tiredness or confusion)
- have a condition which causes excessive release of vasopressin from the brain
- have a condition which is associated with fluid or salt imbalance (abnormal electrolytes), such as nausea, eating disorders, chronic vomiting or diarrhoea, a condition of the adrenal glands (adrenal insufficiency)
- the expiry date printed on the pack has passed
- the package is torn or shows signs of tampering.

Do not give this medicine to children. NOCDURNA is only for use in adults.

Always check the ingredients to make sure you can take this medicine.

Check with your doctor if you:

- have a known allergy to antidiuretic hormone
- are over 65 years or you feel frail (see Section 5. What should I know while taking NOCDURNA? - Things to be aware of)
- have any other medical conditions especially the following:
    - kidney disease
    - diabetes mellitus (high blood sugar)
    - diabetes insipidus (a condition in which the pituitary does not produce antidiuretic hormone)
    - severe bladder dysfunction and problems urinating
    - liver disease
    - heart or blood vessel disease, high blood pressure (hypertension)
    - high blood pressure during pregnancy (pre-eclampsia)
    - systemic infections or fever
    - cystic fibrosis or any other disease which causes fluid or salt imbalance
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

NOCDURNA should only be given to a pregnant woman if the benefits of treatment outweigh the risks.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is recommended that you do not breast-feed while taking NOCDURNA.

The active ingredient in NOCDURNA passes into breast milk. Therefore this medicine is not recommended while you are breast-feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and NOCDURNA may interfere with each other.

Medicines that may increase the effect of NOCDURNA include:

- loperamide, a medicine used to stop diarrhoea
- medications which are known to release antidiuretic hormone (e.g. tricyclic antidepressants, selective serotonine reuptake inhibitors (SSRIs), chlorpromazine or carbamazepine)
- medications which are known to treat high blood sugar (diabetes) as they can increase the risk of fluid buildup in the body, in particular the sulfonylurea group (e.g. chlorpropamide)
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain and inflammation
- diuretics (water or fluid tablets such as thiazides or loop diuretics)
- oxytocin, a medicinal product used in childbirth
- medicines used to treat high blood pressure and some other conditions (ACE inhibitors or angiotensin receptor blockers).

Medicines that may reduce the effect of NOCDURNA include:

- lithium, which is used to treat bipolar disorder

These medicines may be affected by NOCDURNA or may affect how well it works. They may also cause fluid build-up in the body and low sodium levels in the blood, which can make you unwell and is potentially serious.

You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NOCDURNA.

4. How do I take NOCDURNA?

How much to take

- **Women**: 25 micrograms daily, one hour before bedtime.
- **Men**: 50 micrograms daily, one hour before bedtime.

NOCDURNA is placed under the tongue where it dissolves without the need for water.

Follow the instructions provided and take NOCDURNA until your doctor tells you to stop.

When to take

- take NOCDURNA sublingual wafer 1 hour before bedtime.
- **NOCDURNA should not be taken with food since the effect may be reduced.**

How long to take NOCDURNA

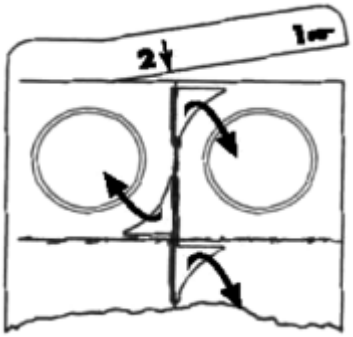
Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine.

Treatment should only be interrupted or stopped on advice of your doctor.

How to take NOCDURNA

1. Completely remove the end tab of a blister strip by tearing along the perforations, starting from the corner with the hand symbol.
2. Now remove one blister from the strip by tearing along the perforations.



3. Remove the foil on each blister, starting at the corner with the printed arrow, by peeling off the foil in the direction of the arrow. Do not push the tablet through the foil.
4. Carefully take a tablet out of its blister. Place the tablet under the tongue and allow it to dissolve. Do not chew or swallow the tablet.
5. If a tablet breaks into more than two pieces while you are taking it out of its blister, do not take the broken pieces. Take a tablet from another blister.

You must limit fluid intake to a minimum from 1 hour before taking NOCDURNA until 8 hours after taking NOCDURNA (see Section 5. What should I know while taking NOCDURNA? - Things to be careful of). If you

experience any of the following symptoms the treatment should be stopped and your doctor contacted: headache, nausea/vomiting, weight gain and, in severe cases, convulsions (see Section 2. What should I know before I take NOCDURNA? - Warnings).

If you are restarting treatment with NOCDURNA, you must go back to following these fluid intake instructions.

In addition, when you restart NOCDURNA, your doctor may again choose to closely monitor the sodium levels in your blood.

Please read the package insert that comes with NOCDURNA prior to use.

If you forget to take NOCDURNA

NOCDURNA should be taken regularly at the same time each day.

If you miss your dose at the usual time, skip the missed dose and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. Continue taking the tablets as usual on the next day.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much NOCDURNA

If you think that you have taken too much NOCDURNA, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include confusion, drowsiness, continuing headache, nausea or vomiting, rapid weight gain due to a build-up of water in the body, or in severe cases, convulsions.

5. What should I know while taking NOCDURNA?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NOCDURNA.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

  It may affect other medicines used during surgery.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine.

  It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests before and after you start treatment with NOCDURNA to make sure that it is safe for you.

Things you should not do

- Do not take NOCDURNA to treat any other complaints unless your doctor tells you to do so.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.
- If you stop taking it suddenly, your condition may worsen.

Things to be careful of

- Restrict drinking fluids from one hour before taking NOCDURNA until at least eight hours after NOCDURNA administration.
- If you need to drink fluids over this period, drink no more than a few sips of water or other fluids.
- A high fluid intake over this period can increase the chance of fluid overload, which can make you feel unwell and is potentially serious.
- Remember to drink normally during the day.
- This is very important to prevent dehydration during daytime.

Things to be aware of

Before your doctor prescribes NOCDURNA for you, you may need to complete a bladder diary, which will involve measuring how much you drink and how much **urine you produce over 24 hours**.

This will help to determine whether your nocturia is caused by an overproduction of urine at night (nocturnal polyuria) or not. You may also be required to complete other tests to rule out other causes.

Your doctor will also need to monitor the level of sodium in your blood before starting treatment, during the first week (4-8 days), one month after you start taking NOCDURNA, and then every 3-6 months or possibly when your other medications are changed or there is a change in your health.

If your sodium levels are found to be too low, your doctor may advise that you stop taking NOCDURNA.

Your doctor or pharmacist can give you more information concerning the above measures.

Driving or using machines

This medicine is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

Keep NOCDURNA sublingual wafers in their original container in order to protect from moisture and light, until it is time to take them.

If you store them out of the blister pack they may not keep well.

Store it in a cool dry place, where the temperature stays below 25°C, away from moisture, heat or sunlight.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date. The expiry date refers to the last day of that month.

6. Are there any side effects?

This medicine helps most people with nocturia, but it may have unwanted side effects in a few people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 65 years of age or you are female you may be at an increased risk of side effects.

This risk is further increased if you are 75 years or older or if you feel frail.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Side effects

Side effects	What to do
Very common side effects (affects one or more in 10 users): • dry mouth. **Common side effects (affects less than 1 in 10 users):** • diarrhoea • dizziness. **Hyponatraemia or low sodium levels in the blood may have the following signs or symptoms:** • headache • stomach (abdominal) pain • nausea. **Hyponatraemia can potentially become a serious side effect, see below.** **Uncommon side effects (affect less than 1 in 100 users):** • weakness (fatigue); generally feeling unwell • stomach (abdominal) discomfort • constipation. **Side effects (unknown frequency):** • muscle cramps	**These side effects are not usually serious but can become serious.** **Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
***Hypersensitivity or allergic reactions:** • shortness of breath, wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin. * This side effect is very rare **Hyponatraemia or low sodium levels in the blood may have the following serious signs or symptoms:** • confusion, drowsiness or decreased consciousness • severe or prolonged headache • nausea or vomiting • rapid weight gain or swelling of hands, ankles or feet (peripheral oedema), which may be due to a build-up of water in the body • convulsions and coma	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NOCDURNA.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NOCDURNA contains

Active ingredient (main ingredient)	desmopressin (desmopressin acetate)
Other ingredients (inactive ingredients)	• gelatin • mannitol • citric acid

NOCDURNA contains either 25 micrograms or 50 micrograms of desmopressin (desmopressin acetate)

Do not take this medicine if you are allergic to any of these ingredients.

What NOCDURNA looks like

NOCDURNA 25 microgram sublingual (under the tongue) wafers are white, round wafers marked with 25 on one side. (AUST R 263596)

NOCDURNA 50 microgram sublingual (under the tongue) wafers are white, round wafers marked with 50 on one side. (AUST R 264292)

NOCDURNA comes in boxes of 10 or 30 sublingual wafers. Each carton contains 1 or 3 aluminium blister trays with 10 sublingual wafers per blister tray.

Who distributes NOCDURNA

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble NSW 2073

This leaflet was prepared in March 2024.

AU-NOC-2400001_v.1.0

NOCDURNA is a registered trademark of Ferring.