NOCDURNA®

Sublingual Wafers

desmopressin (as desmopressin acetate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NOCDURNA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking NOCDURNA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What NOCDURNA is used for

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).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

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

Before you take NOCDURNA

When you must not take it

Do not take NOCDURNA if you have an allergy to:

- any medicine containing desmopressin or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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.

Do not take this medicine if you:

- 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).

Do not breast-feed if you are taking this medicine.

The active ingredient in NOCDURNA passes into breast milk. Therefore this medicine is not

recommended while you are breast-feeding.

Do not give this medicine to children.

NOCDURNA is only for use in adults.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you:

- are over 65 years or you feel frail (see 'Things to be aware of').
- have kidney disease
- have diabetes mellitus (sugar diabetes)
- have diabetes insipidus (a condition in which the pituitary does not produce antidiuretic hormone)
- have a known allergy to vasopressin
- have severe bladder dysfunction and problems urinating
- have liver disease
- have heart or blood vessel disease, high blood pressure (hypertension)
- have high blood pressure during pregnancy (pre-eclampsia)
- have systemic infections or fever
- have cystic fibrosis.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

Your doctor can discuss with you the risks and benefits involved.

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

If you have not told your doctor about any of the above, tell him/ her before you start taking NOCDURNA.

Taking other medicines

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

Some medicines and NOCDURNA may interfere with each other.

It is especially important you tell your doctor if you are taking:

- tricyclic antidepressants, which are medicines used to treat e.g. depression (such as clomipramine, imipramine, desipramine)
- selective serotonine reuptake inhibitors (SSRIs), which are medicines used to treat e.g. depression or anxiety (such as citalopram, paroxetine, sertraline)
- chlorpromazine, which is an anti-psychotic medicinal product used to treat e.g. schizophrenia
- diuretics (water or fluid tablets such as thiazides or loop diuretics e.g. frusemide or other types of diuretics)
- carbamazepine, which is used to treat e.g. bipolar disorder and epilepsy
- antidiabetic medicinal products used for type II diabetes (medicines in the sulfonylurea group), particularly chlorpropamide
- medicines used to treat high blood pressure and some other conditions (ACE inhibitors or angiotensin receptor blockers e.g. enalapril, perindopril, irbesartan etc.)
- non-steroidal anti-inflammatory drugs (NSAIDs), which are medicinal products used for the treatment of pain and inflammation (e.g. aspirin and ibuprofen)
- oxytocin, which is a medicinal product used in childbirth
- lithium, which is used to treat e.g. bipolar disorder
- loperamide, which is a medicinal product used for the treatment of diarrhoea.

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.

Your doctor and pharmacist have more information on medicines to be careful with or to avoid while taking this medicine.

How to take NOCDURNA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

When it is time for your dose:

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 '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 "When you must not take it").

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.

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.

When to take it

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 it

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.

If you forget to take it

Skip the missed dose. Do not take a double dose to make up for the forgotten dose. 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much NOCDURNA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

While you are using NOCDURNA

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NOCDURNA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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 must 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 in order 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 2 days. 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.

Side effects

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

This medicine helps most people with nocturia, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side effects.

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.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice the following and it worries you:

- dry mouth.

This is the most common side effect of your medicine. It is usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- headache
- dizziness
- diarrhoea
- generally feeling unwell
- muscle cramps
- stomach (abdominal) pain or discomfort
- constipation.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- nausea or vomiting
- rapid weight gain (which may be due to a build-up of water in the body)
- severe or prolonged headache
- confusion
- decreased consciousness
- weakness (fatigue)
- swelling of hands, ankles or feet (peripheral oedema)
- convulsions.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using NOCDURNA

Storage

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.

Keep NOCDURNA sublingual wafers in a cool dry place where the temperature stays below 25°C.

Do not store NOCDURNA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP.

The expiry date refers to the last day of that month.

Disposal

If your doctor tells you to stop taking this medicine or the expiry

date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

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

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

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.

Do not use this product if the packaging appears damaged in any way. Do not take the wafers if they appear different from the descriptions above or if they look different in any way.

Ingredients

NOCDURNA contains either 25 micrograms or 50 micrograms of desmopressin (desmopressin acetate) as the active ingredient, and the following inactive ingredients:

- gelatin
- mannitol
- citric acid.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

NOCDURNA is supplied in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1

20 Bridge Street

Pymble NSW 2073

Australia.

AUST R 263596 -

NOCDURNA 25 microgram sublingual wafers

AUST R 264292 -

NOCDURNA 50 microgram sublingual wafers

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