NOCDURNA®

Consumer Medication Information Leaflet (RiMUP)

Oral Lyophilisate for sublingual 25mcg and 50mcg
Desmopressin Acetate 25mcg and 50mcg

What is in this leaflet

What NOCDURNA® is used for

NOCDURNA® is provided as oral lyophilisate in sublingual tablet.
It is used for the treatment of nocturia (frequent need to get up to urinate at night) due to nocturnal polyuria (overproduction of urine during night) in adults.

How NOCDURNA® works

NOCRUDNA contains active ingredient desmopressin which is an antidiuretic, which reduces urine production.

Before you use NOCDURNA®

When you must not use it

DO NOT USE NOCDURNA® if you:

- are allergic to desmopressin or any of the other ingredients in this medicine
- suffer from polydipsia (excessive thirst and increased fluid intake) or psychogenic polydipsia (psychologically caused increased thirst and increased fluid intake)
- have known or suspected cardiac insufficiency (heart failure in which the heart is not able to pump enough blood throughout the body)
- have any disease requiring treatment with diuretics
- have moderately or severely reduced kidney function
- have or have had hyponatraemia (low sodium level in the blood)
- have SIADH (hormone secretion disorder)

Before you start to use it

Check with your doctor before taking NOCDURNA®.

It is especially important that you talk to your doctor before taking NOCDURNA® if:

- you have severe bladder dysfunction and problems urinating
- you are 65 years or older since your doctor will have to monitor the level of sodium in your blood (see the section 3 "How to take NOCDURNA®" below)
- you have low levels of sodium in your blood
- you have a medical condition(s) causing fluid and/or electrolyte imbalance
- you have a medical condition(s) that could be made worse by fluid and/or electrolyte disturbance
- you get an acute intercurrent illness (such as systemic infection, fever, and stomach flu) as it may be necessary for the doctor to interrupt/reassess the treatment with NOCDURNA®
- you have cystic fibrosis, coronary heart disease, high blood pressure, chronic kidney disease or pre-eclampsia

You must limit fluid intake to a minimum from 1 hour before taking NOCDURNA® until 8 hours after taking NOCDURNA®. Treatment without simultaneous reduction of fluid intake may lead to water retention and/or mineral imbalances with or without accompanying warning signs and symptoms hereunder such as headache, nausea/vomiting, weight gain and, in severe cases, convulsions.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

It is especially important you tell it to 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 tablets such as thiazides 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
- 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 around childbirth
- lithium, which is used to treat e.g. bipolar disorder
- loperamide, which is a medicinal product used for the treatment of diarrhoea

NOCDURNA® with food and drink

NOCDURNA® should not be taken with food, since the effect may be reduced.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast- feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will decide if you can use this medicine during pregnancy or if you are breast-feeding.

Driving and using machines

NOCDURNA® has no or negligible

influence on the ability to drive and use machines.

How to use NOCDURNA®
Always take NOCDURNA® exactly as directed by your doctor. Check with your doctor if you are not sure.

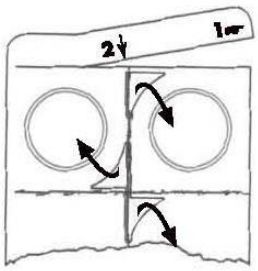
How much to use
The recommended dose is
- women: 25 microgram daily, one hour before bedtime, administered under the tongue without water.
- men: 50 microgram daily, one hour before bedtime, administered under the tongue without water.

NOCDURNA® Oral Lyophilisate for sublingual is placed under the tongue where it is dissolved without the need for water.

Elderly: Treatment of nocturia should not be initiated in patients >65 years.

Instructions for use
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®. If you experience any of the following symptoms the treatment should be stopped and contact your doctor: headache, nausea/ vomiting, weight gain and, in severe cases, convulsion). Your doctor can choose to restart treatment. When restarting treatment, you must strictly restrict fluid intake. In addition, your doctor will closely monitor the sodium levels in your blood.

Use in elderly patients (65 years of age and older)
If you are 65 years or older your doctor will have to monitor the level of sodium in your blood before starting the treatment, during the first week of treatment (4-8 days after initiation of the treatment) and again in about one month after the initiation of the treatment.

Kidney impairment
If you have moderately or severely reduced kidney function, do not take NOCDURNA®. Talk to your doctor.

Liver impairment
If you have impaired liver function you should talk to your doctor before taking NOCDURNA®.

Use in children and adolescents
This medicine is for use in adults only.

When to use it
Always use NOCDURNA® as directed by your doctor.

How long to use it
Continue taking NOCDURNA® for as long as your doctor recommends.

If you forget to use it
Do not take a double dose to make up for a forgotten dose. Continue taking the tablets as usual on the next day.

If you use too much (overdose)
Please consult your doctor.

It is important that you do not take more than the prescribed dose in any 24 hour period. Special attention should be given to signs of hyperhydration of the body (water intoxication), such as weight gain, headache, nausea and in severe cases, convulsions.

While you are using it
Things you must do
Tell any other doctors or pharmacists who are treating you that you are using NOCDURNA®. If you are about to start taking any new medicines, tell your doctor or pharmacist that you are using NOCDURNA®.

Things you must not do
Do not give NOCDURNA® to anyone else, even if they have the same condition as you.

Do not use NOCDURNA® to treat any other complaints unless your doctor has told you to.

Do not stop using NOCDURNA® or lower the dosage, without checking with your doctor or pharmacist.

Things to be careful of
This medicine does not affect your ability to drive and use machines.

If NOCDURNA® makes you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

NOCDURNA®

Oral Lyophilisate for sublingual 25mcg and 50mcg
Desmopressin Acetate 25mcg and 50mcg

Side Effects
Like all medicines, NOCDURNA® can cause side effects, although not everybody gets them.

Drinking too much fluid may lead to a build up of water which dilutes the salt in the body in severe cases. This can become a serious problem and may lead to convulsions.

Stop taking this medicine and tell your doctor immediately or go to your nearest casualty department if you experience one or more of these symptoms,
- an unusually bad or prolonged headache,
- confusion,
- unexplained weight gain,
- nausea or vomiting.

Very common (≥1/10):
- Dry mouth

Common (≥1/100, <1/10):
- Nausea, feeling unwell, muscle weakness and confusion due to decreased level of sodium in the blood (hyponatraemia)
- Headache
- Dizziness
- Nausea
- Diarrhoea

Uncommon (≥1/1000, <1/100):
- Constipation
- Stomach discomfort
- Weakness (fatigue)
- Swelling of the tissue in the lower limbs (peripheral oedema)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumers> Reporting> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of NOCDURNA®
Keep this medicine out of sight and reach of children.

Do not store above 30°C.
Store in the original package in order to protect from moisture and light.
Use immediately upon opening individual tablet blister.

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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product description
What it looks like
NOCDURNA® Oral Lyophilisate for sublingual 25 mcg:
White, round, oral lyophilisate tablet of approximately 12 mm marked with 25 on one side.

NOCDURNA® Oral Lyophilisate for sublingual 50 mcg:
White, round, oral lyophilisate tablet of approximately 12 mm marked with 50 on one side.

Laminated aluminium blister sheets in an outer carton. Each perforated unit dose blister sheet contains 10 oral lyophilisates for sublingual.

Pack sizes:
25mcg: 30 oral lyophilisates.
50mcg: 30 oral lyophilisates.

Ingredients
NOCDURNA® Oral Lyophilisate for sublingual 25 mcg:
Each oral lyophilisate for sublingual contains desmopressin acetate equivalent to 25 mcg desmopressin

NOCDURNA® Oral Lyophilisate for sublingual 50 mcg:
Each oral lyophilisate for sublingual contains desmopressin acetate equivalent 50 mcg desmopressin

Excipients: Gelatin (from fish), mannitol (E421) and citric acid, anhydrous (E330).

MAL number
25 mcg: MAL20116002ACRZ
50 mcg: MAL20116003ACRZ

Manufacturer and Product Registration Holder

Manufacturer
Catalent U.K. Swindon Zydis Limited
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Product Registration holder
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