

NOCTAMID[®] (Noc-TA-mid)

lormetazepam

1 mg tablet

What is in this leaflet

This leaflet answers some common questions about Noctamid. 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 Noctamid 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 is Noctamid used for

Noctamid is used to treat sleeping problems; this includes difficulty in falling asleep.

Noctamid should only be used for short periods.

Noctamid is only indicated when the sleep disorder is severe or causing extreme distress.

Noctamid contains the active ingredient lormetazepam, and belongs to the group of medicines called benzodiazepines. Benzodiazepines increase the action of GABA (a chemical messenger), which helps calm the brain down. This results in promotion of sleep. Benzodiazepines such as Noctamid should be taken for short periods only. If you take Noctamid for too long it may become habit-forming. Benzodiazepines may lead to physical or mental dependence (addiction). If you have any concerns, you should discuss this with your doctor.

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.

Before you take Noctamid

When you must not take it

Do not take Noctamid if:

- you have an allergy to lormetazepam, the active ingredient in Noctamid; or any other benzodiazepines
- you have an allergy to any of the ingredients listed at the end of this leaflet
- you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily).
- you suffer from severe breathing difficulty or have sleep apnoea syndrome (pauses of breathing during sleep)

- you are under the influence of alcohol, medicines used to treat mental illness, strong painkillers

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

You should not take Noctamid if you are under the age of 18 years unless advised by your doctor.

Do not take this medicine after the expiry date printed on the pack and blister. The expiry date is printed on the carton and on each blister after “EXP” (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering. If the packaging 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

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

Tell your doctor if you have or have had any of the following medical conditions as your dose may need to be adjusted:

- liver, kidney or lung disease
- if you suffer from depression or psychosis

Your doctor may need to keep you under close observation.

Tell your doctor if you are pregnant or intend to become pregnant. Noctamid is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.

Tell your doctor if you are breast-feeding or planning to breast-feed. Noctamid should not be administered to breast feeding mothers.

If you have not told your doctor about any of the above, tell them before you start taking Noctamid.

Noctamid contains lactose. If you have been told that you have an intolerance to some sugars, contact your doctor before taking it.

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. Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking Noctamid because its effect may be increased.

Some medicines may interfere with Noctamid. These include:

- medicines used to treat mental illness, depression, anxiety and mood disorders
- medicines which make you drowsy or tired
- strong painkillers and anaesthetics
- medicines used to treat epilepsy
- medicines for allergies that can cause drowsiness (e.g. antihistamines or cold medication)

If narcotic painkillers are taken in combination with Noctamid, enhanced feeling of well-being may occur. This may lead to an increased risk of mental dependence.

These medicines may be affected by Noctamid or may affect how it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist before you take Noctamid.

What else you should know

There may be some loss of the sleep-inducing effect of Noctamid after you have taken Noctamid continuously for a few weeks.

The use of Noctamid or other benzodiazepines may lead to the development of physical and mental dependence upon these products. The risk of dependence increases with dose and duration of treatment; it is also greater if you have a history of alcohol or drug abuse. Therefore, your doctor will carefully consider the risks and benefits, if you have a history of alcohol or drug abuse.

If you have developed a physical dependence and if you stop taking Noctamid abruptly you may experience withdrawal symptoms such as headaches, muscle pain, anxiety, feeling tense, restlessness, confusion and irritability. In severe cases; feeling detached, hallucinations, seizures, tingling or burning sensation in the limbs, sensitivity to light, physical contact, and noise can occur.

You may develop withdrawal symptoms if you are switching from another benzodiazepine to Noctamid.

When you stop taking Noctamid, a passing phase can occur whereby you may experience sleeplessness in an enhanced form (rebound insomnia). Tell your doctor if symptoms come back again in enhanced form.

Since the risk of withdrawal symptoms or rebound insomnia is greater if you stop taking Noctamid abruptly, the dose must be gradually reduced. Your doctor will gradually reduce the amount you take each day to minimise the withdrawal symptoms.

Noctamid may induce a temporary loss of memory (anterograde amnesia). The condition occurs most often in the first few hours after taking Noctamid. Therefore ensure that you will be able to sleep **without interruption** for at least 7 - 8 hours in order to reduce the risk of temporary memory loss.

Reactions like restlessness, agitation, irritability, rages, nightmares, hallucinations, abnormal behaviour and other behavioural disorders are known to occur when using benzodiazepines. Should such reactions occur, see your doctor. You may need to stop using Noctamid. These reactions are more likely to occur in children and the elderly, as well

as in patients with dementia. You should not take Noctamid if you are under the age of 18 years unless advised by your doctor.

Noctamid is not recommended to be used alone for the treatment of sleep disorder associated with depression. Tell your doctor if you have a history of depression, you may need to stop taking Noctamid.

How to take Noctamid

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 pharmacist label, ask your doctor or pharmacist for help.

How much to take

In adults, treatment begins with one Noctamid tablet as a single dose. Elderly patients take half of one Noctamid tablet as a single dose. Under the direction of your doctor, the dose may be doubled in individual cases.

Always take Noctamid exactly as your doctor instructed you. You should check with your doctor or your pharmacist if you are unsure.

If you think that the effect of Noctamid is too strong or too weak, talk to your doctor or pharmacist.

When to take it

Swallow the tablet/s with water before going to bed.

How long to take it

Do not use Noctamid for longer than your doctor says. Usually Noctamid should be used for short periods only (from a few days to two weeks with a maximum of four weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine. Continue taking Noctamid as long as your doctor recommends it.

In certain cases extension beyond the maximum treatment period may be necessary; if so, it should not take place without re-evaluation of your situation.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

If you forget to take it

If you forget to take Noctamid before you go to bed and you wake up late in the night or early morning, do not take any Noctamid as you may have trouble waking in the morning.

Do not take a double dose to make up for forgotten individual doses. This may increase the chance of you getting an unwanted side effect.

If you are unsure what to do, ask your doctor or pharmacist.

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

While you are taking Noctamid

Things you must do

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

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.

Tell your doctor if you notice changes in your behaviour such as depression or suicidal thoughts.

Tell your doctor if you feel Noctamid is not helping your condition.

Visit your doctor regularly. Your doctor needs to check your progress and see whether you need to keep taking Noctamid.

Always discuss with your doctor any problems or difficulties during or after taking Noctamid.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

Do not take Noctamid to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take Noctamid for a longer time than your doctor has prescribed. Noctamid should be taken for short periods only, unless advised otherwise by your doctor.

Do not stop taking your medicine or change the dosage without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. Your doctor will tell you when or if you need to adjust your dosage.

Things to be careful of

Be careful driving or operating machinery until you know how Noctamid affects you. Noctamid may cause forgetfulness or drowsiness that may impair your ability to drive or to

operate machinery. Some people may also experience reduced concentration and impaired muscle function. If you have any of these symptoms, do not drive or operate machinery or do anything else that could be harmful.

Alcohol should be avoided while you are taking this medicine. If you drink alcohol, it may enhance the effects of Noctamid and cause drowsiness.

Even if you take Noctamid at night, you may still be drowsy or dizzy the next day.

Be careful if you are elderly, unwell or taking other medicines. Some people may experience side effects such as drowsiness, dizziness, muscle fatigue and unsteadiness, which may increase the risk of a fall.

In case of an overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 764 766) 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 Noctamid. You may need urgent medical attention.

Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include deep sleep ranging to unconsciousness, shallow breathing, low blood pressure and heart failure.

Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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.

At the start of treatment, drowsiness, mood swings, depressed consciousness, confusion, tiredness, headache, dizziness, muscle weakness, loss of ability to coordinate muscular movements and double vision may occur; these usually disappear with continued treatment.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- feeling anxious
- decreased sexual drive
- dizziness
- unusual tiredness or weakness
- drowsiness

- disturbance in attention
- loss of memory (amnesia)
- visual impairment such as double vision
- speech disorder
- abnormal sense of taste
- slowed thinking
- vomiting
- feeling sick (nausea)
- stomach pain
- constipation
- dry mouth
- itchy rash
- sweating
- difficulty in urinating

The above list includes the common side effects of your medicine.

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

- fast or irregular heart beat
- rapid swelling of skin and mucous membranes, which can lead to airway obstruction (angioedema)

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

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

- signs of an allergy such as rash; itching or hives on the skin; swelling of the face; lips, tongue or other parts of the body; shortness of breath, wheezing or trouble breathing

These very serious side effects are rare. If you have these side effects you may need urgent medical attention.

Cases of suicides and suicide attempts have been reported in patients with depression taking Noctamid and other benzodiazepines. Tell your doctor if you have a history of depression, you may need to stop taking Noctamid.

The use of Noctamid and other benzodiazepines may lead to the development of physical and mental dependence; sleeplessness in an enhanced form; nightmares and abnormal behaviour such as delusions or rages.

Benzodiazepines, including Noctamid, may increase the risks of falls, particularly in the elderly. Tell your doctor if you experience loss of ability to coordinate muscular movements, muscle weakness, dizziness, drowsiness or tiredness, as these side effects can increase your risk of falls.

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 Noctamid

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the box or blister pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

Do not leave it 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.

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.

Return any unused medicine to your pharmacist.

Product Description

What it looks like

Noctamid 1 mg tablets are white, round tablets and 7 mm in diameter. They are scored on one side and with an indented "CF" in a regular hexagon on the other side. Noctamid 1 mg tablets are available in packs containing 30 tablets.

Ingredients

Active ingredient:

- Noctamid – 1 mg lorazepam per tablet

Inactive ingredients:

- lactose
- maize starch
- magnesium stearate
- polyvidone 25 000

Sponsor Details

Made in Germany for:

Bayer New Zealand Limited
3 Argus Place, Hillcrest
North Shore AUCKLAND 0627
Free phone: 0800 233 988

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This leaflet was last revised on 18 November 2011.

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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