

PACKAGE LEAFLET: INFORMATION FOR THE USER

Noctamid® 1mg Tablets
(lormetazepam)

Your medicine is available using the name Noctamid 1mg Tablets but will be referred to as Noctamid throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What Noctamid is and what it is used for
- What you need to know before you take Noctamid
- How to take Noctamid
- Possible side effects
- How to store Noctamid
- Contents of the pack and other information

1. What Noctamid is and what it is used for

Noctamid contains lormetazepam, which belongs to the group of medicines called benzodiazepines.

- Noctamid helps to
- shorten the time it takes for you to fall asleep
 - reduce the frequency of awakening in the night
 - prolong your sleep time without making you feel tired or drowsy the next day.

Your doctor will prescribe Noctamid for a short time only when your sleep problems are severe, disabling or causing extreme distress.

2. What you need to know before you take Noctamid

Do not take Noctamid:

- if you have a particular condition in which the **muscles become weak** and tire easily (myasthenia gravis)
- if you have severe **breathing difficulty** (respiratory insufficiency e.g. severe chronic obstructive disease)
- if your **breathing sometimes stops** when you are asleep (sleep apnoea syndrome)
- if you have taken an excessive amount of alcohol or other drugs (e.g. sleeping tablets, painkillers or drugs used to treat psychiatric illness)
- if you are **allergic** to this type of drug or any of the other ingredients of this medicine (listed in section 6).

Tell your doctor before you take Noctamid if any of these applies to you.

Warnings and precautions

- Talk to your doctor before taking Noctamid if:
- you have long term **lung disease** (respiratory insufficiency). You may need a lower dose than other patients as Noctamid can interfere with your breathing.
 - you have severely reduced liver function (hepatic insufficiency). Special care is needed because drugs such as Noctamid can increase symptoms such as loss of memory, loss of consciousness, personality changes and difficulty with concentration (possible symptoms of encephalopathy). If you have liver problems, your doctor might give you a lower dose.
 - you have severe **kidney problems**. You may need to be observed more closely while taking Noctamid.
 - you have spinal or cerebellar ataxia, where parts of the nervous system that control movement are damaged.

You are **more likely to fall** while taking these tablets, especially if you are an older patient. This is because of some of the side effects of Noctamid, such as loss of coordination, muscle weakness, dizziness, sleepiness and tiredness. Noctamid should be used for **as short a period as possible**. You may find that Noctamid becomes less effective after you have taken it for a few weeks (**tolerance**).

Taking Noctamid can lead to you becoming dependent on the drug (**physical or psychological dependence**). This is more likely with higher doses or if you take Noctamid for a long time. It is also more likely if you have a history of alcohol or drug abuse. Noctamid must be used extremely carefully if you have a history of alcohol or drug abuse.

- If you have become dependent on Noctamid and you then suddenly stop taking it you will suffer **withdrawal symptoms**. These may include:
- extreme anxiety
 - tension
 - restlessness
 - confusion
 - irritability
 - headaches
 - muscle pain

- In severe cases you may:
- feel out of touch with reality
 - feel strange in familiar surroundings
 - have hallucinations
 - have numbness and tingling of your arms and legs
 - become over-sensitive to light, noise, sound and physical contact
 - have epileptic seizures.

It is possible with some drugs of this type that withdrawal symptoms may start between one dose and the next. This is very unlikely to happen with Noctamid. However, if you have taken a similar drug before starting Noctamid, you may develop these withdrawal symptoms when you start taking Noctamid.

When you stop taking Noctamid, you may find it difficult to sleep for some time (**rebound insomnia**). Tell your doctor if this happens. You are less likely to suffer from withdrawal symptoms or rebound insomnia if you reduce the dose of Noctamid gradually.

Noctamid may cause a short term loss of memory (anterograde amnesia). This occurs most often in the first few hours after taking the tablets. **Make sure that you will be able to sleep without interruption for at least 7-8 hours** in order to reduce this risk.

Stop taking the tablets and see your doctor if you have reactions like restlessness, agitation, irritability, aggressiveness, delusion, rages, nightmares, hallucinations, psychoses or inappropriate abnormal behaviour (**psychiatric and paradoxical reactions**). These reactions are more likely to occur in children, in the elderly and in patients with dementia (organic brain syndrome).

Noctamid is not recommended as the main treatment for psychotic illness.

Noctamid should not be used alone to treat sleep disorders associated with depression.

Tell your doctor if you are suffering from depression. Depression may be unmasked during use of drugs like Noctamid. This may lead to suicidal tendencies.

Children and adolescents

Noctamid should not be given to patients younger than eighteen years unless it is essential. Your doctor will carefully assess the need for treatment in younger patients. If there is a need to take Noctamid it must be taken for the shortest possible time.

Elderly patients

Elderly patients may need a lower dose of Noctamid.

For further information, see Section 3 'How to take Noctamid'.

Other medicines and Noctamid

- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed. The effects of Noctamid may be increased if Noctamid is taken at the same time as other drugs which affect your central nervous system, such as:
- alcohol
 - drugs used to treat psychosis
 - some medicines for depression, anxiety and mood disorders (antidepressant agents, anxiolytics/sedatives)
 - strong painkillers (opioids) and anaesthetics
 - medicines used for epilepsy
 - medicines used to treat allergies (antihistamines), some of which may cause sleepiness (sedation).

If certain kinds of painkillers (opioid analgesics) are taken with Noctamid, it may affect your mood. This may increase the risk of you becoming dependent.

- Your doctor will also take special care, especially at the beginning of treatment with Noctamid, if you are also prescribed
- beta-blockers (used to treat irregular heart beat and high blood pressure) since these substances may enhance the calming effect of Noctamid
 - cardiac glycosides (used to treat heart failure by clogging and irregular heart beat) since their effect may be increased
 - methylxanthines (caffeine, theophylline) since these substances may reduce the calming effect
 - estrogen-containing medicinal products (e.g. hormonal contraceptives, hormonal replacement therapy) since these substances may reduce the calming effect
 - Rifampicin (antibiotic) since rifampicin may reduce the calming effect.

Noctamid with food and drink

Do not take Noctamid at the same time as you drink alcohol. The effects may be increased.

Pregnancy and breast-feeding

Do not take Noctamid if you are pregnant or while delivering a baby. Tell your doctor straight away if you are pregnant or think you might be pregnant or if you intend to become pregnant. You may have to stop taking Noctamid.

If your doctor has decided that you should receive this medicine during late pregnancy or during labour and delivery, your baby might have a low body temperature, weak muscles, low blood pressure and breathing and feeding difficulties.

If you take Noctamid or similar drugs regularly in late pregnancy, your baby may become dependent and may have withdrawal symptoms.

Do not take Noctamid when you are breast-feeding, since small amounts of the drug may enter the breast milk. Tell your doctor if you are breast-feeding.

Driving and using machines

Noctamid affects your ability to drive and use machines. It makes you sleepy and forgetful. It may also reduce your concentration and interfere with your muscle function. If affected, do not drive or operate machinery.

Noctamid contains lactose

If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this product.

3. How to take Noctamid

Always take this medicine exactly as your doctor told you. Check with your doctor or pharmacist if you are not sure.

Take Noctamid for as short a period as possible. Usually this will vary from a few days up to two weeks with a maximum of four weeks. This includes the period during which the dose is gradually reduced.

In certain cases treatment may be continued for longer. This should only happen after your doctor has examined your situation.

Dose

Adults usually start with 1mg Noctamid as a single dose. Older patients take 0.5mg Noctamid as a single dose. Your doctor may decide to increase the dose, up to twice as much, in some cases.

Take the tablets with some liquid shortly before going to bed.

For patients with mild to moderate difficulties in breathing or patients with liver impairment, a dose reduction should be considered.

Use in children and adolescents

Do not take Noctamid if you are under 18 years of age unless your doctor considers it essential. The dose for patients under 18 years of age depends on your age, weight and general condition. It should be used for as short a period as possible.

Talk to your doctor or pharmacist if you think that the effect of Noctamid is too strong or too weak.

If you take more Noctamid than you should, contact your doctor, pharmacist or hospital immediately.

Taking too much Noctamid does not usually present a threat to life. However, if you have also taken other drugs or alcohol, you may have difficulty in breathing. In rare cases this has led to coma and in very rare cases, death.

If you have taken too much Noctamid, you may feel drowsy or tired. You may also have problems with your coordination (ataxic symptoms) and vision.

Higher doses may cause deep sleep or unconsciousness, problems with breathing and low blood pressure.

If you have milder symptoms your doctor may decide to let you sleep them off while someone is taking care of you. If larger amounts have been taken, it may be necessary to make you vomit or give other treatment.

A drug called flumazenil may be useful to reverse the effects of overdose.

If you forget to take Noctamid

Do not take a double dose to make up for a forgotten dose. Wait until the correct time to take the next dose and then take only the dose that has been prescribed.

If you stop taking Noctamid

You may experience withdrawal symptoms if you have become dependent on Noctamid and then stop treatment suddenly. For more information see Section 2 ‘Take special care with Noctamid’.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Side effects are listed below by how common they are.

Very common (may affect more than 1 user in 10):

- headache.

Common (may affect 1 to 10 users in 100):

- rapid swelling of the skin or the lining of the mouth and throat which can lead to obstruction of your airways (angioedema)
- feeling anxious
- reduced sex drive
- dizziness, sedation, sleepiness, reduced attention, loss of memory (amnesia), problems with your sight or speech, an unusual sense of taste (dysgeusia), slowed thinking
- fast heart rate
- vomiting, feeling sick (nausea), upper stomach pain, constipation, dry mouth
- itching (pruritis)
- difficulty passing urine
- reduced vitality (asthenia)
- excessive sweating

Frequency not known:

- completed suicide and suicide attempts (unmasking of pre-existing depression)
- acute psychosis
- hallucination
- dependence
- depression (unmasking of pre-existing depression)
- delusion
- when you stop taking your tablets, you may suffer from increased difficulty in sleeping (rebound insomnia)
- agitation
- aggression
- irritability
- restlessness
- anger
- nightmares
- abnormal behaviour
- emotional disorders
- confusion
- reduced alertness
- loss of coordination of muscular movements (ataxia)
- muscular weakness
- red, itching skin (urticaria)
- rash
- tiredness (fatigue)
- falls

If you have become dependent and you suddenly stop taking Noctamid, you may have **withdrawal symptoms**. These include extreme anxiety, tension, restlessness, confusion, irritability, headaches, and/or muscle pain. In severe cases you may feel out of touch with reality, feel strange in familiar surroundings, or have hallucinations, numbness or tingling of your hands and feet. You may also become very sensitive to light, noise and physical contact or have epileptic seizures.

For more information, see **Section 2: Take Special Care with Noctamid**.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Noctamid

Keep out of the sight and reach of children.

Do not store above 25°C.
Do not use Noctamid after the expiry date (‘Exp’) which is stated on the blister and carton. The expiry date refers to the last day of that month.
If your tablets appear to be discoloured or show any other signs of deterioration, please return to your pharmacist who will advise you further.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Noctamid contains

Each tablet contains 1mg of lormetazepam.
The other ingredients are: lactose, maize starch, povidone 25000 and magnesium stearate.

What Noctamid looks like and contents of the pack

Noctamid is a round, white tablet with ‘CF’ imprinted in a hexagon on one face and a breakline on the reverse.
The tablet can be divided into equal halves.
Noctamid is available in packs of 30 tablets.

Manufacturer

Manufactured by: Delpharm Lille SAS, Z.I. de Roubaix Est, Rue de Toufflers, 59390 Lys-Lez-Lannoy, France
or Bayer OY, PO Box 415, 20101 Turku, Finland
or Bayer OY, Pansiontie 47, 20210 Turku, Finland.

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