

NYTAMEL 5mg Film-coated Tablets

NYTAMEL 10mg Film-coated Tablets

Zolpidem tartrate

Read all of this leaflet carefully before you start taking 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.

In this leaflet

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1. What Nytamel is and what it is used for

Nytamel is a hypnotic belonging to the group of benzodiazepine-like agents. It is indicated for short-term treatment of sleep disturbances.

Treatment with benzodiazepines and benzodiazepine-like agents is only indicated in sleep disturbances of clinically relevant severity

2. What you need to know before you take Nytamel

DO NOT take Nytamel

- if you are allergic to zolpidem tartrate or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from certain forms of pathologic muscle weakness (myasthenia gravis)
- in case of short-term respiratory arrest while you are sleeping (sleep apnoea syndrome)
- if you suffer from severe breathing weakness (respiratory insufficiency)
- if you suffer from severe liver damage (hepatic insufficiency).

Children and adolescents of less than 18 years of age must not take Nytamel.

Warnings and precautions

Talk to your doctor or pharmacist before taking Nytamel.

General

Before treatment with Nytamel

- the cause of the sleep disturbances should be clarified
- underlying diseases should be treated

If treatment of the sleep disturbances is not successful after 7 – 14 days, this might point to a psychiatric or physical basic disease which should be checked.

General information about effects observed after use of benzodiazepines and benzodiazepine-like agents (such as Nytamel) or other hypnotics which the prescribing doctor should consider is described in the following:

Habituation

After repeated intake over several weeks the sleep-promoting (hypnotic) effect can be attenuated.

Dependence

Development of physical and psychological dependence is possible.

The risk increases with the dose and duration of treatment and is elevated in patients with previous alcohol or drug abuse. If physical dependence has developed, sudden discontinuation of treatment is accompanied by withdrawal symptoms.

Withdrawal symptoms (rebound insomnia)

After hypnotic treatment is terminated, a transient syndrome may occur with the sleep disturbances recurring in an enhanced form (rebound phenomenon). It may be accompanied by other reactions: headache or muscle pain, extreme anxiety and tension, restlessness, confusion, irritability and sleep disturbances and in severe cases derealisation, depersonalisation, auditory defects (hyperacusis) numbness and tingling of extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures may occur.

It is important that you are aware of the possibility of such symptoms in order to minimize your anxiety.

Next-day psychomotor impairment (see also Driving and using machines)

The day after taking Nytamel, the risk of psychomotor impairment, including impaired driving ability may be increased if:

- You take this medicine less than 8 hours before performing activities that require your alertness
- You take a higher dose than the recommended dose
- You take zolpidem while you are already taking another central nervous system depressant or another medicine that increases zolpidem in your blood, or while drinking alcohol, or while taking illicit substances.

Take the single intake immediately at bedtime.

Do not take another dose during the same night.

Memory defects (amnesia)

Memory defects may be induced (anterograde amnesia).

This condition generally occurs some hours after intake of Nytamel. In order to minimize this risk, you should make sure that an uninterrupted sleep of 7 – 8 hours will be possible (see 4. “Possible side effects”).

Psychiatric and “paradoxical” reactions

Restlessness, inner restlessness, irritability,

aggressivity, delusions (psychoses), rages, nightmares, hallucinations, sleepwalking, inappropriate behaviour, increased sleep disturbances and other adverse behavioural effects are known to occur during treatment.

Should this occur, Nytamel should be discontinued. These reactions are more likely to occur in the elderly.

Special Patient groups

Benzodiazepines and benzodiazepine-like agents (such as Nytamel) should be administered with care in

Elderly, and debilitated patients

They should receive a lower dose (see 3. “How to take Nytamel”). Nytamel has a muscle-relaxant effect. For this reason, especially elderly patients are at risk of falling and consequently of hip joint fractures when getting out of bed at night.

Patients with impaired renal function

Although no dose adjustment is necessary, caution is required.

Patients with chronic dyspnoea

It is proven that benzodiazepines can impair breathing. It should be considered as well that anxiety or inner restlessness have been described as signs of dyspnoea.

Patients with alcohol and drug abuse in their medical history

Extreme caution is required. These patients should carefully be supervised during treatment with Nytamel, as they are at risk of habituation and psychological dependence.

Benzodiazepines and benzodiazepine-like agents (such as Nytamel) are not indicated for

- Patients with severe liver dysfunctions. They are at risk of brain damage (encephalopathy).
- Patients with delusions (psychoses) for primary treatment.
- The treatment of depression or anxiety accompanied by depression alone (risk of suicide).

Other medicines and Nytamel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Nytamel should be used with caution in combination with other medicinal products depressing the central nervous system (see 2. “What you need to know before you take Nytamel”).

While taking zolpidem with the following medicines, drowsiness and next-day psychomotor impairment effects, including impaired driving ability, may be increased.

- Medicines for some mental health problems (neuroleptics, antidepressants, antipsychotics)
- Medicines for sleep problems (hypnotics)
- Medicines to calm or reduce anxiety (anxiolytics/sedatives)
- Medicines for depressions
- Medicines for moderate to severe pain (narcotic analgesics). Increased euphoria may occur which can result in increased psychological dependence.
- Medicines for epilepsy (antiepileptics)
- Medicines used for anaesthesia
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines).

While taking zolpidem with antidepressants including bupropion, desipramine, fluoxetine, sertraline and venlafaxine, you may see things that are not real (hallucinations).

It is not recommended to take zolpidem with fluvoxamine or ciprofloxacin.

Medicinal agents enhancing the activity of certain liver enzymes can reduce the effect of Nytamel: e.g. Rifampicin (for the treatment of tuberculosis).

Please note that these statements may also apply to medicines used some time ago or at some time in the future.

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

Nytamel with food, drink and alcohol

You should not consume any alcohol during treatment, as this will change and intensify the effect of zolpidem in an unforeseeable way. The ability to perform tasks that demands an increased concentration is additionally impaired by this combination.

Pregnancy and breast-feeding

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.

Nytamel should not be taken during pregnancy, especially not in the first trimester because no sufficient data is available to evaluate safe administration of Nytamel during pregnancy and the lactation period. Although Nytamel did not show any malformations or any effect damaging the embryo in animal studies, the safety during human pregnancy has not been verified.

Please inform your doctor if you want to become pregnant during treatment with Nytamel or if you suspect to be pregnant, so that he/she can decide whether treatment is to be continued or i.e. converted.

If Nytamel is taken for a longer-term period during the last months of pregnancy, withdrawal symptoms may occur in the newborn after delivery.

If Nytamel is taken for compelling medicinal reasons towards the end of pregnancy or during delivery, effects such as reduced body heat (hypothermia), low blood pressure (hypotension) and moderate respiratory depression may occur in the newborn.

Since zolpidem passes into mother's milk in low quantities, Nytamel should not be taken during the lactation period.

Driving and using machines

Nytamel has major influence on the ability to drive and use machines such as “sleep driving”. On the day after taking Nytamel (as other hypnotic medicines), you should be aware that:

- You may feel drowsy, sleepy, dizzy or confused
- Your quick decision-making may be longer
- Your vision may be blurred or double
- You may be less alert

A period of at least 8 hours is recommended between taking zolpidem and driving, using machinery and working at heights to minimize the above listed effects.

Do not drink alcohol or take other psychoactive substances while you are taking Nytamel, as it can increase the above listed effects.

Nytamel contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Nytamel

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

The recommended dose is:

Adults

The recommended dose per 24 hours is 10 mg of Nytamel. A lower dose may be prescribed to some patients. Nytamel should be taken:

- as a single intake,
- just before bedtime

Make sure you have a period of at least 8 hours after taking this medicine before performing activities that require your alertness.

Do not exceed 10 mg per 24 hours.

Elderly and debilitated patients

In elderly or debilitated a dose of 1 film-coated tablet of Nytamel 5 mg (corresponding to 5 mg zolpidem tartrate)/day is recommended.

The dose should only be increased to 2 film-coated tablets of Nytamel 5 mg (corresponding to 10 mg zolpidem tartrate)/day if the effect is insufficient and the medicinal product is tolerated well.

Patients with impaired liver function

In patients with impaired liver function a dose of 1 film-coated tablet of Nytamel 5 mg (corresponding to 5 mg zolpidem tartrate)/day is recommended.

The dose should only be increased to 2 film-coated tablets of Nytamel 5 mg (corresponding to 10 mg zolpidem tartrate)/day if the effect is insufficient and the medicinal product is tolerated well.

Maximum dose

A daily dose of 2 film-coated tablet of Nytamel 5 mg (corresponding to 10 mg zolpidem tartrate)/day should not be exceeded.

Children and adolescents

Nytamel must not be used in children and adolescents of less than 18 years of age.

Method and route of administration

The film-coated tablet should be taken together with liquid immediately before going to bed.

How long should you take Nytamel?

The duration of administration should be as short as possible. In general, it could be a few days up to 2 weeks and not exceed 4 weeks the stepwise withdrawal phase included.

The withdrawal phase should be chosen on an individual basis.

Certain situations may require prolongation beyond the maximum time of treatment. Your attending doctor will decide on that after renewed evaluation of your complaints.

If you take more Nytamel than you should.

In case of overdosage, a doctor's advice is to be asked without delay.

In case of overdosage of Nytamel alone, depression of consciousness has been reported which was in the range from extreme sleepiness up to light coma.

If you forget to take Nytamel

Do not take a double dose to make up for a forgotten dose. Continue intake of Nytamel as prescribed by your doctor.

If you stop taking Nytamel

As the risk of withdrawal symptoms is higher after abrupt discontinuation of treatment, your doctor will advise you to terminate treatment by gradual reduction in the dose.

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.

The following frequency data is the basis for the evaluation of side effects:

Very common: may affect more than 1 in 10 people,
common: may affect up to 1 in 10 people,
uncommon: may affect up to 1 in 100 people,
rare: may affect up to 1 in 1,000 people,
very rare: may affect up to 1 in 10,000 people, including isolated cases.

Psychiatric disorders

Uncommon: Paradoxical reactions: Restlessness, psychomotor restlessness, irritability, aggressiveness, delusions, rage, nightmares, hallucinations, psychoses, sleepwalking, inappropriate behaviour and other adverse behavioural effects (such reactions are more likely to occur in the elderly), memory defects (amnesia), which may be associated with inappropriate behaviour (see “Warnings and precautions”).

Pre-existing depression may become manifest during use of benzodiazepines or benzodiazepine-like agents. Use (even at therapeutic dosages) may lead to physical dependence: discontinuation of the therapy may result in withdrawal or rebound phenomena (see “Warnings and precautions”). Psychological dependence may occur. Abuse has been reported in polydrug abusers.

Decrease in sexual need (libido).

Nervous system disorders

Common: Sleepiness during the following day, numbed emotions, reduced alertness, confusion, tiredness, headache

Eye disorders

Common: Double vision

Ear and labyrinth disorders

Common: Dizziness, disorders of movements (ataxia)

Gastrointestinal disorders

Uncommon: Gastrointestinal disturbances (diarrhoea, nausea, vomiting)

Skin and subcutaneous tissue disorders

Uncommon: Skin reactions

Musculoskeletal, connective tissue and bone disorders

Common: Muscle weakness

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 Nytamel

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and blister. The first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Store in the original package.

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.

6. Contents of the pack and other information

What Nytamel contains:

The active substance is zolpidem tartrate. Each film-coated tablet contains 5 mg or 10 mg zolpidem tartrate.

The other ingredients are:

Tablet core: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (type A), hypromellose and magnesium stearate.

Tablet coating: titanium dioxide (E171), hypromellose and macrogol 400.

What Nytamel looks like and contents of the pack:

Nytamel 5 mg film-coated tablets are white to off-white, oval, biconvex, film-coated tablets and engraved with “ZIM” and “5” on one side. Nytamel 10 mg film-coated tablets are white to off-white, oval, biconvex, film-coated tablets, scored on both sides and engraved with “ZIM” and “10” on one side. The tablet can be divided into equal halves.

Pack sizes: 4, 5, 7, 10, 14, 15, 18, 20, 25, 28, 30, 40, 50, 60, 70, 80, 90, 100, 150 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd,
Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturers

Centrafarm Services B.V.,
Etten-Leur, The Netherlands

STADA Arzneimittel AG,
Stadastrasse 2–18, D-61118 Bad Vilbel, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	Mondeal 10 mg filmtabletten
Belgium:	Zolpidem EG 10 mg
Germany:	Zolpidem STADA 5 mg and 10 mg filmtabletten
Denmark:	Zonoct 10 mg
Ireland:	Nytamel 5 mg and 10 mg tablets
Luxembourg:	Zolpidem EG 10 mg filmomhulde tabletten
The Netherlands:	Zolpidemtartraat STADA 5 mg and 10 mg, filmomhulde tabletten
Sweden:	Zolpidem STADA

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