Package leaflet: Information for the user

Nytamel 5 mg Film-coated tablets
Nytamel 10 mg 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.

What is in this leaflet

1. What Nytamel is and what it is used for
Zolpidem belongs to a group of medicines known as benzodiazepine-like agents.

Nytamel are sleeping pills (hypnotics) which work by acting on the brain to cause sleepiness. It is used for short-term treatment of insomnia in adults, only when the disorder is severe, disabling or causing great distress for the patient.

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 below). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- if you have ever experienced sleep walking or other behaviours which are unusual while sleeping, (such as driving, eating, making a phone call or having sex etc.) while not being fully awake after taking Nytamel or other medicines containing zolpidem
- 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 acute and/or severe breathing problems (respiratory failure)
- if you have severe liver problems (hepatic insufficiency).

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Nytamel if
- you have liver problems
- you have kidney problems
- you have breathing problems (respiratory insufficiency)
- you have depression or have had another mental illness, anxiety or psychotic illness in the past. Zolpidem may unmask or worsen symptoms.
- you have or have ever had thoughts of harming or killing yourself

Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.
- you have recently taken Nytamel or other zolpidem-containing medicines for more than 4 weeks
- you are elderly or frail. If you get up at night, take care. Nytamel may relax your muscles. This and the sedative effect increases your risk of falling and consequently of hip fractures. Your doctor may prescribe you a lower dose (see section 3. "How to take Nytamel")
- you have ever had any heart problems including slow or uneven heartbeat
- you have abused or have been dependent on alcohol or drugs.

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 depressants 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.

Other considerations
- **Habituation** – If, after a few weeks, you notice that your tablets are not working as well as they did when you first started treatment, you should see your doctor.
- **Dependence** – When taking this type of medicine there is a risk of abuse and dependence, which increases with dose and length of treatment. The risk is greater if you have a history of psychiatric disorders or drug dependence, alcohol, substance or drug abuse. However, dependence may also occur at doses normally used for treatment or if you do not show risk factors such as a history of alcohol or drug abuse.
- **Withdrawal** – Treatment should be withdrawn gradually. A short-lived syndrome may occur on withdrawal, whereby the symptoms that led to your treatment with Nytamel recur in an enhanced form (withdrawal phenomenon). It may be accompanied by other reactions including mood changes, anxiety and restlessness. You may also suffer from such symptoms in between doses when taking this medicine, especially when the dosage is high.
- **Amnesia** – This medicine can cause memory loss. To reduce this risk you should ensure that you are able to have 8 hours uninterrupted sleep.
- **Psychiatric and "paradoxical" reactions** – Nytamel can cause behavioural side effects such as restlessness, agitation, irritability, aggressiveness, delusions (false beliefs), rages, nightmares, hallucinations (when you see, hear or feel things that are not there), psychoses, inappropriate behaviour and increased insomnia.
- **Sleep walking and other associated behaviours** – This medicine can cause people to do things whilst asleep that they do not remember when they wake up. This includes sleep walking, sleep driving, preparing and eating food, making phone calls or having sex without being fully awake. Stop taking this medicine and talk to your doctor as soon as possible if you experience such behaviours. Alcohol and some medicines used to treat depression or anxiety or the use of Nytamel at doses exceeding the maximum recommended dose can increase the risk of these side effects.
- **Risk of falling and severe injuries** – This medicine can cause drowsiness and a decreased level of consciousness, which may increase the risk of falls and consequently to severe injuries (see also section 4. "Possible side effects").

If following a 7-14 day course of treatment, symptoms of insomnia persist, contact your doctor so that your treatment can be re-evaluated.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Nytamel.

Children and adolescents
This medicine is not recommended to be used in children and adolescents under 18 years of age.

Other medicines and Nytamel
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Nytamel can affect the way some other medicines work. Also, some medicines can affect the way Nytamel works.

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

Concomitant use of Nytamel and opioids (strong painkillers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your doctor does prescribe Nytamel together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tell your doctor if you are taking any of the following medicines:
While taking Nytamel with the following medicines, drowsiness and next-day psychomotor impairment effects, including impaired driving ability, may be increased.
- Medicines for some mental health problems (antipsychotics)
- Medicines for sleep problems (hypnotics)
- Medicines to calm or reduce anxiety
- Medicines for depressions
- Medicines for moderate to severe pain (narcotic analgesics)
- Medicines for epilepsy
- Medicines used in anaesthesia
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines)

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

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

<u>The following medicines can increase the chance of you getting side effects when taken with Nytamel:</u>
- Medicines which inhibit liver enzymes. Ask your doctor or pharmacist which medicines have this effect (e.g. ketoconazole, a medicine used to treat fungal infections).

To make this less likely, your doctor may decide to lower your dose of Nytamel.

<u>The following medicines can make Nytamel work less well:</u>
- Rifampicin (an antibiotic) - for infections
- St John's Wort (an herbal medicine) – for mood swings and depression – use of Nytamel and St John's Wort together is not recommended

Nytamel with food, drink and alcohol

Do not consume alcohol while you are being treated with Nytamel. Alcohol can increase the effects of Nytamel and make you sleep very deeply so that you do not breathe properly or have difficulty waking up.

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 for advice before taking this medicine.

Use of Nytamel is not recommended during pregnancy.

If used during pregnancy, there is a risk that the baby is affected. Some studies have shown that there may be an increased risk of cleft lip and palate (sometimes called "harelip") in the newborn baby.

Reduced foetal movement and foetal heart rate variability may occur after taking Nytamel during the second and/or third trimester of pregnancy.

If Nytamel is taken at the end of pregnancy or during labour, your baby may show muscle weakness, a drop in body temperature, difficulty feeding and breathing problems (respiratory depression). If this medicine is taken regularly in late pregnancy, your baby may develop physical dependence and may be at risk of developing withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

You should not take Nytamel if you are breast-feeding. This is because small amounts may pass into breast milk.

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 minimise 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.

For more information about possible side effects which could affect your driving see section 4 of this leaflet.

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

Adults
The recommended dose per 24 hours is 10 mg of Nytamel. A lower dose may be prescribed to some patients.
Nytamel 10 mg film-coated tablets can be divided into equal doses (5 mg each) along the score line.

Elderly and debilitated patients
The usual dose is 5 mg zolpidem tartrate taken just before bedtime. Your doctor may decide to increase your dose to 10 mg zolpidem tartrate if the effect is insufficient and the medicine is well tolerated.

Patients with liver problems
The usual starting dose is 5 mg zolpidem tartrate taken just before bedtime. Your doctor may decide to increase your dose to 10 mg zolpidem tartrate if the effect is insufficient and the medicine is well tolerated. Do not take Nytamel if you have severe liver problems.

Maximum dose
A daily dose of 10 mg zolpidem tartrate must not be exceeded in any case.

Use in children and adolescents
Nytamel is not recommended to be used in children and adolescents under 18 years of age.

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

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.

How long you should 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.

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.
If you take more Nytamel than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. Do not go unaccompanied to seek medical help.

Taking too much Nytamel can be very dangerous. The following effects may happen:
- Feeling drowsy, confused, sleeping deeply and possibly falling into a fatal coma

If you forget to take Nytamel
Nytamel must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day. Only take the missed dose if you are still able to have 8 hours of uninterrupted sleep. If this is not possible, take the next dose before bedtime the next night. Do not take a double dose to make up for a forgotten dose.

If you stop taking Nytamel
Treatment should be withdrawn gradually, otherwise the symptoms you are treated for may return more intensely than before (rebound insomnia). Also, anxiety, restlessness and mood changes may occur. These effects will disappear in time.

If you have become physically dependent to Nytamel, sudden withdrawal of treatment will lead to side effects such as headaches, muscle pain, anxiety, tension, restlessness, confusion, irritability and sleeplessness. In severe cases other effects may appear, such as hypersensitivity to light, noise and physical contact, abnormally acute hearing and painful sensitivity to sound, hallucinations, numbness and tingling of the extremities, derealisation (feeling the world around you is not real), depersonalisation

(feeling your mind is becoming separated from your body) or epileptic seizures (violent fitting or shaking). These symptoms may also be experienced between doses, especially if the dose is high.

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.

Stop taking Nytamel and see a doctor or go to a hospital straight away if:
- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue (angioedema). The frequency of this side effect is not known (frequency cannot be estimated from the available data).

Other side effects that may occur

Common (may affect up to 1 in 10 people)
- Memory disorders such as poor memory (amnesia), memory impairment, inability to recall the recent past (anterograde amnesia). This is more likely to affect you in the few hours after you take this medicine. By having 8 hours sleep after taking Nytamel, this is less likely to cause you a problem.
- Sleeping problems that get worse after taking this medicine
- Seeing or hearing things that are not real (hallucinations)
- Drowsiness or a strong desire to sleep (may also occur during the following day)
- Dizziness
- Blurred eyesight or double vision
- Diarrhoea
- Feeling sick (nausea) or being sick (vomiting)
- Abdominal pain
- Infection of the lungs or airways (respiratory infection)
- Headache
- Feeling tired
- Feeling agitated
- Nightmares
- Depression
- Back pain
- Reduced alertness
- Movements disorders (ataxia)
- 'Spinning' sensation (vertigo)

Uncommon (may affect up to 1 in 100 people)
- Change in appetite (appetite disorder)
- Sleep driving and other strange behaviour (sleep walking, having sex whilst asleep)
- Feeling of intense elation or confidence (euphoria)
- Gait disturbance and falling, especially in the elderly
- Feeling confused or irritable
- Feeling restless or angry
- Disturbance in attention
- Speech difficulties
- Pains in your joints or muscles, muscle spasms
- Neck pain
- Unusual sensation or tingling of skin (paraesthesia)
- Tremor
- Change in the amount of liver enzymes (elevated) - shown up in the results of blood tests
- Itching skin or skin rash
- Excessive sweating

- Weak muscles

Rare (may affect up to 1 in 1,000 people)
- Decreased ability to see (visual impairment)
- Being less aware of your environment
- Changes in sex drive (libido)
- Hives
- Liver damage (hepatocellular, cholestatic or mixed forms)

Very rare (may affect up to 1 in 10,000 people)
- Dependence on Nytamel in which you feel you need to take it to feel normal (see section 2 'Warnings and precautions')
- Breathing difficulties (respiratory depression)
- Thinking things that are not true (delusions)

Not known (frequency cannot be estimated from the available data)
- Feeling angry or showing unusual behaviour
- Nytamel having less effect than normal (habituation, see section 2 "Warnings and precautions")

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, Website: www.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.
One film-coated tablet contains 5 mg zolpidem tartrate.
One film-coated tablet contains 10 mg zolpidem tartrate.

The other ingredients are:
Tablets core: lactose monohydrate, microcrystalline cellulose, type A sodium starch glycolate, hypromellose and magnesium stearate,
Film 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 and imprinted with "ZIM" and "5" on one side.
Nytamel 10 mg Film-coated tablets are white to off-white, oval, film-coated, scored on both sides imprinted with "ZIM" and "10" on one side. Nytamel 10 mg film-coated tablets can be divided into equal doses (5 mg each) along the score line.

Nytamel Film-coated tablets are available in:

- cartons containing 4, 5, 7, 10, 14, 15, 20, 25, 28, 30, 40, 50, 60, 70, 80, 90, 100, 150 or 500 tablets packed in blisters.
- tablet containers containing 30, 100 or 500 tablets, sealed with a childproof closure.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturers
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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 filmomhulde tabletten
Germany	Zolpidem STADA 5/10 mg Filmtabletten
Denmark	Zonoct, filmovertrukne tabletter
Ireland	Nytamel 5/10 mg
Luxembourg	Zolpidem EG 10 mg comprimés pelliculés
Sweden	Zolpidem STADA

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