PACKAGE LEAFLET
Zopiclone tablets are sleeping pills (hypnotics) which work by acting on the brain to cause sleepiness. Zopiclone may be used for the short term treatment of difficulty in sleeping which is severe, disabling or causing great distress in adults.

2. What you need to know before you take Zopiclone

Do not take Zopiclone if you:

- are allergic (hypersensitive) to zopiclone or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include a rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue
- suffer from a disease of the muscles causing drooping eyelids, double vision, difficulty speaking and swallowing and sometimes muscle weakness in the arms and legs (myasthenia gravis)
- have severe liver problems
- suffer from irregular breathing while asleep (sleep apnoea syndrome)
- have severe breathing problems
- are under the age of 18.

Warnings and precautions

Talk to your doctor or pharmacist before taking Zopiclone if you:

- are elderly or at risk of becoming confused. Taking zopiclone may mean an increased risk of falling and consequential injuries
- suffer from liver or kidney problems, as your doctor may start you on a lower dose
- have a history of breathing problems. Taking zopiclone will reduce the force of
your breathing

- suffer from or have a history of depression, anxiety or psychotic illness. Zopiclone may cause the symptoms to reappear or worsen
- have or ever had a history of alcohol or drug abuse (see also ‘Dependence’ below)
- have been told by a doctor that you have a personality disorder (see also ‘Dependence’ below).

Other considerations when taking Zopiclone are:

- Dependence – when taking this type of medicine there is a risk that you may develop some dependence. This risk increases with the time for which you have been taking zopiclone and your dosage. There is also a greater risk in those patients who have history of alcohol or drug abuse or personality disorders.
- Amnesia – taking zopiclone can cause memory loss. To avoid this make sure that when you take Zopiclone you will be able to have 7-8 hours of uninterrupted sleep.

Other medicines and Zopiclone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially any of the following:

- Medicines used to treat certain mental and emotional conditions (antipsychotics)
- Hypnotic medicines
- Other sleeping pills (sedatives)
- Medicines used to treat depression (antidepressants)
- Medicines to treat anxiety (anxiolytics)
- Strong medicines used to relieve pain (narcotic analgesics), such as codeine and morphine, which may increase the risk of side effects and could lead to dependency
- Medicines that reduce liver function, such as erythromycin, clarithromycin, ketoconazole, fluconazole, itraconazole, tacrolimus and ritonavir. Ask your doctor or pharmacist which medicines have this effect
- Medicines that increase liver function, such as rifampicin, nefazodone, phenobarbital, phenytoin and St John’s wort. Ask your doctor or pharmacist which medicines have this effect
- Medicines used to treat epilepsy such as carbamazepine
- Antihistamine medicines which can cause sleepiness
- Anaesthetic medicines and muscle relaxants, which may be used during surgery
- Metoclopramide, used to relieve sickness
- Medicines containing atropine.

Zopiclone with alcohol

You should not drink alcohol while being treated with this medicine, because this may increase the sedative effects of zopiclone. This may persist to the following morning and affect your ability to drive.

Pregnancy and breast-feeding

Pregnancy
Zopiclone should not be used during pregnancy unless clearly necessary. If for urgent
medical reasons, you take zopiclone during late pregnancy or during labour, your baby may show withdrawal symptoms after birth because of physical dependence.

Breast-feeding
Do not breast-feed your baby, as small amounts of zopiclone can pass into breast milk.

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.

Driving and using machines
Do not drive, operate machinery or perform other tasks requiring mental alertness if you feel dizzy or drowsy, or you have eyesight problems while taking this medicine especially the morning after taking. If you have just started treatment with Zopiclone do not drive or use machines until you are sure that it is safe to do so. Zopiclone may make you feel drowsy, cause loss of concentration including memory problems or muscle weakness.

Zopiclone contains lactose
If your doctor has told you that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Zopiclone

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

The recommended dose is:

**Adults**
1 tablet (7.5 mg) immediately before going to bed. This dose should not be exceeded.

**Elderly, frail or those patients with reduced kidney, liver or lung function**
A starting dose of 3.75 mg (half a tablet) is recommended, with the tablets being taken immediately before going to bed.

**Use in children and adolescents**
Zopiclone should not be given to children and adolescents under the age of 18 years. The safety and efficacy of zopiclone in children and adolescents aged less than 18 years have not been established.

If after a few weeks you notice that the tablets are not working as well as they did at the start of treatment, you should see your doctor as your dose may need to be adjusted.

The tablet should be taken by mouth with a glass of liquid, immediately before going to bed.

**How long should you take Zopiclone for**
The duration of treatment with Zopiclone should be as short as possible. Generally
treatment should last from between a few days to up to two weeks. Treatment should not
exceed 4 weeks, including a period of tapering off.

Your doctor will choose a withdrawal regime based on your individual needs. In some
cases it may take longer than the recommended maximum time of treatment.

If you take more Zopiclone than you should
Contact your doctor or nearest hospital emergency department immediately, do not go
unaccompanied to seek medical help. If an overdose has been taken you may become
increasingly drowsy very quickly. Take the container and any remaining tablets with you.
Symptoms of overdose can range from extreme drowsiness to coma. These symptoms can
be magnified when combined with alcohol.

If you forget to take Zopiclone
If you forget to take a dose immediately before going to bed but remember during the night
only take the missed dose if you are still able to have 7-8 hours uninterrupted sleep. If this
is not possible, take the next dose before bed time the next night. Do not take a double dose
to make up for a forgotten dose.

If you stop taking Zopiclone
Treatment with zopiclone should be gradually withdrawn, as the symptoms that
Zopiclone was used to treat may return with a higher intensity (rebound insomnia). Other
such withdrawal symptoms could include anxiety, restlessness and mood changes, these
will however disappear with time.

If you have become physically dependent on Zopiclone, sudden withdrawal of treatment
could lead to symptoms such as headaches, tension, muscle pain, confusion, anxiety,
tremor, sweats, agitation, palpitation, fast heart rate, nightmares, panic attacks, muscle
aches and cramps, upset stomach, restlessness and irritability. In severe cases symptoms
may also include hypersensitivity to light, noise and physical contact, hallucinations,
epileptic seizures, personality disturbances, numbness of the extremities and the feeling
that the world around you is not real (derealisation).

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.

If any of the following happen, stop taking Zopiclone and tell your doctor
immediately or go to your nearest hospital emergency department:
• Skin rash, itching
• Swelling of the face, lips, throat or tongue
• Difficulty breathing or swallowing.
These allergic reactions are rare but serious. You may need medical attention.

- Psychiatric and ‘paradoxical’ reactions – zopiclone can cause restlessness, agitation, irritability, aggression, delusion, outbursts of rage, nightmares, hallucinations, psychoses, unsuitable behaviour and other behavioural disturbances. If you experience any of these symptoms you should stop taking Zopiclone.
- Sleepwalking and associated behaviours – zopiclone can cause behaviours such as sleepwalking, ‘sleep driving’, preparing and eating food or making phone calls whilst not fully awake and with no memory of these actions. These can occur more commonly if you drink alcohol or take other sleeping pills or medicines to treat anxiety. If you experience any of these symptoms you should stop taking Zopiclone.
- Loss of memory (amnesia) to avoid this make sure you will be able to have 7-8 hours of uninterrupted sleep before taking this medicine
- Difficulty breathing, including very slow or shallow breathing

Other side effects may include:

Common (may affect up to 1 in 10 people):
- Sleepiness during the following day
- Reduced alertness
- Bitter taste in the mouth
- Dry mouth

Uncommon (may affect up to 1 in 100 people):
- Fatigue
- Nightmares
- Agitation
- Headaches
- Feeling sick (nausea)
- Vomiting
- Dizziness

Rare (may affect up to 1 in 1,000 people):
- Numbness emotions
- Confusion
- Falls, which may be more likely in older people
- Irritability
- Aggressiveness
- Hallucinations (seeing, hearing and/or feeling things that are not there)
- Psychoses
- Changes in sexual drive (libido)
- Shortness of breath

Very rare (may affect up to 1 in 10,000 people)
- Changes in liver functions, which may be seen in blood tests

Not known (frequency cannot be estimated from the available data):
• Dependence
• Restlessness
• Fixed irrational ideas, not shared by others (delusions)
• Anger
• Depressed mood
• Sleepwalking, and associated behaviours (which you may have no memory of)
• Uncontrollable movements
• Double vision
• Indigestion
• Muscle weakness
• Light-headedness
• Feeling uncoordinated
• Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin

Report of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via Yellow Card scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zopiclone

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 outer carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C and keep 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 Zopiclone contains
The active substance is zopiclone. Each film-coated tablet contains 7.5 mg zopiclone. The other ingredients are lactose anhydrous (see section 2, ‘Zopiclone contains lactose’), calcium hydrogen phosphate anhydrous, maize starch, povidone, magnesium stearate and hypromellose. The printing ink contains titanium dioxide (E171) and macrogol 400.

What Zopiclone looks like and contents of the pack
Your medicine comes as a white film-coated tablet with a breakline. The tablet can be divided into equal halves. The tablets are marked ‘ZZ’ on one side and ‘7.5’ on the other.
Zopiclone is available in blisters of 5, 7, 10, 14, 20, 21, 28, 30, 56, 60, 84, 90 and 100 tablets. Zopiclone is also available in a bulk pack of 100 or 500 tablets in a polypropylene container. Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

**Manufacturer**
Generics [UK] Limited, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

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