Zopiclone Tablets are a group of medicines called hypnotics (sleeping tablets). These tablets can be used for both temporary and longer-lasting sleep problems (insomnia). They can help you to sleep, without leaving you drowsy the next day. However, Zopiclone is not meant to be used every day for long periods of time. If you need any further information on your condition, please ask your doctor.

WHAT ZOPICLONE TABLETS ARE AND WHAT THEY ARE USED FOR

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WHAT YOU NEED TO KNOW BEFORE YOU TAKE ZOPICLONE TABLETS

Do not take Zopiclone:

- if you are allergic to Zopiclone or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swelling of the lips, tongue, face or throat.

Warnings and precautions

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

- suffer from myasthenia gravis (a condition where the muscles easily tire and become weak)
- have any breathing problems, especially during sleep (sleep apnoea)
- suffer from respiratory failure (your lungs do not work properly)
- have severe liver problems
- are under 18 years of age

Please tell your doctor before taking this medicine if you:

- have a personality disorder
- have ever been, or are currently being treated for drug or alcohol abuse
- have a personality disorder
- have severe liver problems
- are under 18 years of age

Other medicines and Zopiclone

Please inform your doctor or pharmacist if you are taking, have recently taken, or have recently started taking any other medicine including medicines obtained without a prescription. If you are taking any other medicines, these medicines may change the effects, which could affect your driving, see section 4 of this leaflet.

Children and adolescents

Do not give this medicine to children or adolescents under 18 years of age as the safety of Zopiclone has not yet been established in this age group.

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Pregnancy and breast-feeding

Always take this medicine exactly as your doctor or pharmacist has told you. Do not change the frequency of taking the medicine, how much you take, or the length of time you take it, even if your condition improves. The number of tablets you need to take will depend on your condition.

Zopiclone Tablets are NOT recommended for women of child-bearing age. If you are breast-feeding, do not take this medicine while you are breast-feeding. Do not give this medicine to children or a child swallows any tablets, go to your nearest casualty department.

On the day after taking Zopiclone 7.5mg Tablets, do not drive or use machinery or tools if you feel sleepy, dizzy or confused.

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

The recommended dose is:

- Adults
- 3.75mg per day.
- Elderly
- 3.75mg per day.

Use in Children and adolescents

Zopiclone Tablets are NOT recommended for children.

Your treatment will usually be for less than 4 weeks, and the doctor may reduce your dose near the end of your course. If you take Zopiclone for longer than this, the medicine may not work as well, you may become dependent and you may have withdrawal symptoms if you stop. If you have the impression that the effect of Zopiclone Tablets is too strong or too weak talk to your doctor or pharmacist.

If you take more of this medicine than you should

If you have taken more Zopiclone Tablets than you should, or a child swallows any tablets, go to your nearest casualty department.

If you take more Zopiclone Tablets than you should, or a child swallows any tablets, go to your nearest casualty department.
If you forget to take your medicine
Zopiclone must only be taken before going to bed. If you forget to take a dose just take the next tablet at the usual time. DO NOT take two doses at the same time.

If you stop taking this medicine
It is important to continue taking the tablets for as long as your doctor tells you to. You should not stop taking your tablets suddenly without advice from your doctor. Do not change the dose of your medicine unless you have spoken with your doctor.

Your doctor will need to lower your dose before stopping your treatment to help prevent any withdrawal effects and to help prevent return of your sleep problems (rebound insomnia).

Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects when duration of treatment is limited to 4 weeks.

Withdrawal symptoms
Some patients may experience withdrawal symptoms when they stop taking this medicine. See a doctor immediately if you get any of the following symptoms:

- Headaches
- Muscle pain
- Sweating
- Stomach problems
- Restless grip on reality
- Faster or uneven heartbeat
- Numbness and tingling sensation in hands and feet
- Increased sensitivity to light, noise and physical contact
- Feeling of watching yourself
- A higher level of awareness and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Feeling anxious, shaky, irritable, agitated, confused or having panic attacks
- Epileptic Seizures
- Rare cases of abuse have been reported

Possible side effects
The following side effects have been reported:

- COMMON
  - Headaches
  - Muscle pain
  - Sweating
  - Sleepiness
  - Dry mouth
  - Nausea (feeling sick)
  - Drowsiness
  - Stomach discomfort
  - Headache
  - Nightmares
  - Dry mouth
  - Dizziness
  - Nausea (feeling sick)
  - Drowsiness
  - Stomach discomfort

- UNCOMMON
  - Headache
  - Nightmares
  - Somnolence (sleepiness)
  - Nausea
  - Vomiting (being sick)
  - Insomnia
  - Fatigue
  - Tiredness
  - Agitation

- RARE (may affect up to 1 in 10 people)
  - Mild bitter taste or metallic taste in the mouth
  - Dry mouth
  - Sleepiness
  - Dry mouth
  - Nausea (feeling sick)
  - Vomiting (being sick)
  - Constipation
  - Tiredness
  - Agitation

- VERY RARE (may affect up to 1 in 10,000 people)
  - Poor memory since taking Zopiclone
  - Confusion
  - Libido disorder
  - Hallucinations - seeing or hearing things that are not real
  - Mood changes such as irritability or aggressiveness
  - Falls, especially the elderly

- NOT KNOWN (frequency cannot be estimated from the available data)
  - Restlessness
  - Anger
  - Muscle Weakness
  - Loss of co-ordination
  - Loss of memory
  - Double vision
  - Unusual skin sensations such as numbness, burning, tingling or prickling (paresthesia)
  - Difficult concentrating or paying attention
  - Disrupted normal speech
  - Indigestion

- BECOMING dependent
- Sleepwalking

Sleep-driving and other strange behaviour
There have been some reports of people doing things while asleep that they do not remember when waking up after taking a sleep medicine. This includes sleep-driving and sleepwalking. Alcohol and some medicines for depression or anxiety can increase the change that this serious effect will happen.

Reporting 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 the Yellow Card Scheme, Website: 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 TABLETS

KEEP THIS MEDICINE OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not use this medicine after the expiry date printed on the blister and carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not keep the tablets if your doctor decides to stop treatment.

Do not throw away any medicines via wastewa- ter 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 PACK AND OTHER INFORMATION

What your medicine contains
The active ingredient is zopiclone hydrochloride. Each tablet contains 7.5mg of zopiclone. The inactive ingredients are calcium hydrogen phosphate dihydrate, lactose monohydrate, maize starch, cellulose, hydroxypropyl methyl cellulose, croscarmellose sodium, magnesium stearate, hydroxypropyl methyl cellulose, propylene glycol, titanium dioxide and talc.

What your medicine looks like and contents of the pack
Zopiclone 7.5mg Tablets are white coloured, circular, film-coated tablets with a score line on one side. The tablets are available in a pack size of 28.

Marketing Authorisation Holder
Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.
Telephone: 00 353 (0) 9066 61109
Fax: 00 353 (0) 9066 61121

For any information about this medicine, please contact Athlone Laboratories on the contact details above.

Manufacturer responsible for batch release
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Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7TD, U.K.

Distributor
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