PATIENT INFORMATION LEAFLET
ZOPICLONE 7.5mg TABLETS

Do not take Zopiclone if:

• You are allergic to Zopiclone or any of the other ingredients of this medicine (listed in section 6).
• You have severe liver problems.
• You take Zopiclone while already taking another central nervous system depressant or another medicine that reduces alertness.
• You take Zopiclone with alcohol.
• You take Zopiclone while already taking a medicine that reduces alertness.
• You have recently taken Zopiclone or other similar medicines.
• You feel you will not be able to stop taking Zopiclone.
• You have a personality disorder.
• You have a history of mental disorders and/or alcohol, illicit substance or drug abuse.

If you stop taking this medicine

• Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects.
• The risk of psychomotor dependence. In this case the newborn should be monitored closely for the postnatal period.
• If you stop taking this medicine during the last 3 months of pregnancy, there could be effects on the child.
• If used during pregnancy there is a risk to the baby’s life.
• In this case the newborn should be monitored closely for the postnatal period.

If you stop taking this medicine

• Do not take Zopiclone if:

• You have severe liver problems.
• You take Zopiclone while already taking another central nervous system depressant or another medicine that reduces alertness.
• You take Zopiclone with alcohol.
• You take Zopiclone while already taking a medicine that reduces alertness.
• You have recently taken Zopiclone or other similar medicines.
• You feel you will not be able to stop taking Zopiclone.
• You have a personality disorder.
• You have a history of mental disorders and/or alcohol, illicit substance or drug abuse.

If you stop taking this medicine

• Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects.
• The risk of psychomotor dependence. In this case the newborn should be monitored closely for the postnatal period.
• If you stop taking this medicine during the last 3 months of pregnancy, there could be effects on the child.
• If used during pregnancy there is a risk to the baby’s life.
• In this case the newborn should be monitored closely for the postnatal period.

If you stop taking this medicine

• Do not take Zopiclone if:

• You have severe liver problems.
• You take Zopiclone while already taking another central nervous system depressant or another medicine that reduces alertness.
• You take Zopiclone with alcohol.
• You take Zopiclone while already taking a medicine that reduces alertness.
• You have recently taken Zopiclone or other similar medicines.
• You feel you will not be able to stop taking Zopiclone.
• You have a personality disorder.
• You have a history of mental disorders and/or alcohol, illicit substance or drug abuse.

If you stop taking this medicine

• Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects.
• The risk of psychomotor dependence. In this case the newborn should be monitored closely for the postnatal period.
• If you stop taking this medicine during the last 3 months of pregnancy, there could be effects on the child.
• If used during pregnancy there is a risk to the baby’s life.
• In this case the newborn should be monitored closely for the postnatal period.

If you stop taking this medicine

• Do not take Zopiclone if:

• You have severe liver problems.
• You take Zopiclone while already taking another central nervous system depressant or another medicine that reduces alertness.
• You take Zopiclone with alcohol.
• You take Zopiclone while already taking a medicine that reduces alertness.
• You have recently taken Zopiclone or other similar medicines.
• You feel you will not be able to stop taking Zopiclone.
• You have a personality disorder.
• You have a history of mental disorders and/or alcohol, illicit substance or drug abuse.

If you stop taking this medicine

• Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects.
• The risk of psychomotor dependence. In this case the newborn should be monitored closely for the postnatal period.
• If you stop taking this medicine during the last 3 months of pregnancy, there could be effects on the child.
• If used during pregnancy there is a risk to the baby’s life.
• In this case the newborn should be monitored closely for the postnatal period.

If you stop taking this medicine

• Do not take Zopiclone if:

• You have severe liver problems.
• You take Zopiclone while already taking another central nervous system depressant or another medicine that reduces alertness.
• You take Zopiclone with alcohol.
• You take Zopiclone while already taking a medicine that reduces alertness.
• You have recently taken Zopiclone or other similar medicines.
• You feel you will not be able to stop taking Zopiclone.
• You have a personality disorder.
• You have a history of mental disorders and/or alcohol, illicit substance or drug abuse.

If you stop taking this medicine

• Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects.
• The risk of psychomotor dependence. In this case the newborn should be monitored closely for the postnatal period.
• If you stop taking this medicine during the last 3 months of pregnancy, there could be effects on the child.
• If used during pregnancy there is a risk to the baby’s life.
• In this case the newborn should be monitored closely for the postnatal period.

If you stop taking this medicine

• Do not take Zopiclone if:

• You have severe liver problems.
• You take Zopiclone while already taking another central nervous system depressant or another medicine that reduces alertness.
• You take Zopiclone with alcohol.
• You take Zopiclone while already taking a medicine that reduces alertness.
• You have recently taken Zopiclone or other similar medicines.
• You feel you will not be able to stop taking Zopiclone.
• You have a personality disorder.
• You have a history of mental disorders and/or alcohol, illicit substance or drug abuse.

If you stop taking this medicine

• Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects.
• The risk of psychomotor dependence. In this case the newborn should be monitored closely for the postnatal period.
• If you stop taking this medicine during the last 3 months of pregnancy, there could be effects on the child.
• If used during pregnancy there is a risk to the baby’s life.
• In this case the newborn should be monitored closely for the postnatal period.

If you stop taking this medicine

• Do not take Zopiclone if:

• You have severe liver problems.
• You take Zopiclone while already taking another central nervous system depressant or another medicine that reduces alertness.
• You take Zopiclone with alcohol.
• You take Zopiclone while already taking a medicine that reduces alertness.
• You have recently taken Zopiclone or other similar medicines.
• You feel you will not be able to stop taking Zopiclone.
• You have a personality disorder.
• You have a history of mental disorders and/or alcohol, illicit substance or drug abuse.

If you stop taking this medicine

• Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects.
• The risk of psychomotor dependence. In this case the newborn should be monitored closely for the postnatal period.
• If you stop taking this medicine during the last 3 months of pregnancy, there could be effects on the child.
• If used during pregnancy there is a risk to the baby’s life.
• In this case the newborn should be monitored closely for the postnatal period.

If you stop taking this medicine

• Do not take Zopiclone if:

• You have severe liver problems.
• You take Zopiclone while already taking another central nervous system depressant or another medicine that reduces alertness.
• You take Zopiclone with alcohol.
• You take Zopiclone while already taking a medicine that reduces alertness.
• You have recently taken Zopiclone or other similar medicines.
• You feel you will not be able to stop taking Zopiclone.
• You have a personality disorder.
• You have a history of mental disorders and/or alcohol, illicit substance or drug abuse.

If you stop taking this medicine

• Stopping treatment with Zopiclone Tablets is unlikely to be associated with withdrawal effects.
• The risk of psychomotor dependence. In this case the newborn should be monitored closely for the postnatal period.
• If you stop taking this medicine during the last 3 months of pregnancy, there could be effects on the child.
• If used during pregnancy there is a risk to the baby’s life.
• In this case the newborn should be monitored closely for the postnatal period.

If you stop taking this medicine

• Do not take Zopiclone if:

• You have severe liver problems.
• You take Zopiclone while already taking another central nervous system depressant or another medicine that reduces alertness.
• You take Zopiclone with alcohol.
• You take Zopiclone while already taking a medicine that reduces alertness.
• You have recently taken Zopiclone or other similar medicines.
• You feel you will not be able to stop taking Zopiclone.
• You have a personality disorder.
• You have a history of mental disorders and/or alcohol, illicit substance or drug abuse.
Patients with liver or kidney problems

The usual starting dose is 7.5mg (1 tablet).

Patients with Respiratory Insufficiency

A reduced dosage is recommended.

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 longer than this, the medicine may not work as well, you may become dependent and you may have withdrawal symptoms when you stop.

If you have the impression that the effect of Zopiclone Tablets is too strong or too weak at the doctor's or pharmacist’s discretion.

If you take more of this medicine than you should

If you have taken more Zopiclone Tablets than you should, or if the medicine is no longer needed, go to your nearest casualty department immediately. Take the medicine pack with you as the doctor knows what you have taken.

If you are taking Zopiclone while already taking another central nervous system depressant or another sedative and hypnotic, the risk of dependence increases. The risk of dependence increases the longer you take Zopiclone Tablets.

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 this medicine suddenly without advice from your doctor. Do not change the dose of your medicine unless you have spoken with your doctor.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your pharmacist if you are not sure. The number of tablets in the package is shown on the container. To dispose of tablets, follow your local waste disposal instructions.

Before taking Zopiclone Tablets, ensure that you take the doctor’s dosage recommendations closely.

Do not take this medicine if you:

- are elderly as there may be a greater risk of side effects
- have recently taken Zopiclone or other similar medicines
- feel you will not be able to stop taking Zopiclone Tablets
- have a personality disorder
- have recently had surgery
- are allergic to one or more of the ingredients
- have severe poisoning
- have treated for drug or alcohol abuse
- have a history of dependency to other medicines
- have used Zopiclone Tablets while taking medicine such as antibiotics to treat infections
- are pregnant or breast-feeding
- have a disease that makes you more likely to become dependent
- have taken Zopiclone longer than this, the medicine may not work as well, you may become dependent and you may have withdrawal symptoms when you stop.

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 this medicine suddenly without advice from your doctor. Do not change the dose of your medicine unless you have spoken with your doctor.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your pharmacist if you are not sure. The number of tablets in the package is shown on the container. To dispose of tablets, follow your local waste disposal instructions.

Before taking Zopiclone Tablets, ensure that you take the doctor’s dosage recommendations closely.

Do not take this medicine if you:

- are elderly as there may be a greater risk of side effects
- have recently taken Zopiclone or other similar medicines
- feel you will not be able to stop taking Zopiclone Tablets
- have a personality disorder
- have recently had surgery
- are allergic to one or more of the ingredients
- have severe poisoning
- have treated for drug or alcohol abuse
- have a history of dependency to other medicines
- have used Zopiclone Tablets while taking medicine such as antibiotics to treat infections
- are pregnant or breast-feeding
- have a disease that makes you more likely to become dependent
- have taken Zopiclone longer than this, the medicine may not work as well, you may become dependent and you may have withdrawal symptoms when you stop.

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
- Difficulty sleeping
- Numbness and tingling in hands and feet
- Increased sensitivity to light, noise and physical contact
- Feeling of watching yourself

Depersonalization

- A lowered level of symptoms and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real
- Feeling of nausea or feeling sick
- Feeling anxious or agitated
- Confused or having panic attacks
- Epileptic Seizures
- Rare cases of abuse have been reported

4. POSSIBLE SIDE EFFECTS

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

If you experience the following rare, but very serious side effects, stop taking Zopiclone Tablets and tell your doctor immediately or contact the casualty department at your nearest hospital:

- An allergic reaction: skin rash, swelling of the face, lips, tongue or throat or difficulty breathing or swallowing or light headedness or co-ordination, delusions (thinking that things are not real), depression, feeling low or sad, and respiratory depression (slower breathing) including these signs and symptoms

Tell your doctor or pharmacist if any of the following side effects occur or worsen:

- The following side effects have been reported:

Common (may affect up to 1 in 10 people)
- Mild bitter taste or metallic taste in the mouth
- Dry mouth

Uncommon (may affect up to 1 in 100 people)
- Headache
- Nightmares
- Stomach discomfort
- Nausea (feeling sick)
- Vomiting (being sick)
- Dizziness
- Tiredness (physically or mentally)
- Agitation

Rare (may affect up to 1 in 10,000 people)
- Poor memory since taking Zopiclone
- The doctor
- Libido disorders
- Hallucinations - seeing or hearing things that are not real
- Mood changes such as irritability or aggressiveness
- Fat, especially the abdomen
- Hot, lumpy rash (urticaria)

Very Rare (may affect up to 1 in 10,000 people)
- Change in blood tests (increase of liver activity in the blood)
- Not known (frequency cannot be estimated from the available data)
- Rash/pustules
- Delusion
- Anger
- Muscle weakness
- Loss of co-ordination
- Loss of memory
- Double vision
- Unusual skin sensations such as numbness, burning
- Feeling dizzy or thinking not as sharp
- Difficulty concentrating or paying attention
- Disordered normal speech
- Indigestion
- Becoming dependent
- Sweating or body weight decrease

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 risk that this serious effect will happen.

Reporting of side effects

If you get any unexpected side effects, talk to your doctor or pharmacist.

This includes any possible side effect not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 return unused medicine to the pharmacy.

If you take the tablets if your doctor decides to stop treatment.

Do not throw away any medicines or waste material in household waste. Ask your pharmacist how to throw away medicines you no longer need. These measures will help protect the environment.

6. PACK CONTENTS OF OTHER PACKAGING

What your medicine contains

The active ingredient is zopiclone. Each tablet contains 7.5mg of zopiclone.

The inactive ingredients are calcium hydrogen phosphate diphosphate, lactose monohydrate, magnesium stearate, talc, magnesium stearate, silicon dioxide, hypromellose, microcrystalline cellulose, hydroxypropyl methylcellulose, povidone, glycol and titanium dioxide.

What your medicine looks like and contents of the pack

Zopiclone 7.5mg Tablets are white oval tablets with a score line on one side.

The tablets are available in a pack size of 28.

Marketing Authorisation Holder

Aptivus Pharmaceuticals Limited, Ballymoyr, Co. Dublin, Ireland. Telephone: 035 333 906110
Fax: 035 333 906111

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

Manufacturer responsible for batch quality

Kent Pharmaceuticals Limited, Crowborough Road, Ashford, Kent, TN24 9GR, U.K.

Kent Pharmaceuticals Limited, Rapton Road, Maidstone, ME14 2TJ, U.K.

PL 304640127

This leaflet was revised in May 2020.