Zopiclone 3.75mg and 7.5mg Tablets

Before taking Zopiclone tablets, it is important to make sure that you can have at least 7 to 8 hours of uninterrupted sleep to help reduce the risk of some side effects (see section 4 - Possible side effects).

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

Use of Zopiclone tablets may lead to the development of abuse and psychological dependence. The risk of dependence increases with dose and duration of treatment and is greater when Zopiclone tablets are used for longer than 4 weeks, and in patients with history of mental disorders and/or alcohol, drug abuse or drug dependence. Tell your healthcare provider if you have ever had a mental disorder, or have abused or been dependent on alcohol, substance or drugs.

Children and adolescents

Zopiclone tablets should not be used in children.

Other medicines and Zopiclone tablets

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

The following medicines may increase the sedating effect of Zopiclone tablets:
• Medicines to treat mental illness (antipsychotics)
• Medicines to treat depression
• Medicines used to treat epilepsy
• Anesthetics (used during surgery)
• Medicines to calm or reduce anxiety or for sleep problems (hypnotics)
• Medicines for thyreotoxicosis or other allergies that can make you sleep (relative antihistamines) such as chlorphenamine or promethazine
• Concomitant use of Zopiclone tablets and opioids (strong pain killers, 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 Zopiclone tablets 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 close 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.
• Some medicines for moderate to severe pain (non-sedative) such as codeine, methadone, morphone, oxydendine, pethidine or tramadol.

The following medicines can increase the chance of you getting side effects when taken with Zopiclone tablets. To make the less likely, your doctor may decide to lower your dose of Zopiclone tablets:
• Some antibiotics such as clarithromycin or erythromycin
• Some medicines for fungal infections such as ketoconazole and itraconazole
• Radiotherapy (a prostate inhibitor) - for prostate infections

The following medicines can make Zopiclone tablets work less well:
• Some medicines for epilepsy such as carbamazepine, phenobarbital or phenytoin
• Some medicines for bacterial infections
• St John's Wort (herbal medicine) - for mood swings and depression

Zopiclone tablets with alcohol

Alcohol should not be consumed when taking Zopiclone tablets, as the sedating effect may be increased.

Pregnancy, breast-feeding and fertility

Pregnancy

Use of Zopiclone tablets is not recommended during pregnancy if you are pregnant, think you may be pregnant or planning to have a baby. Ask your doctor for advice. During pregnancy there is a risk to the baby if Zopiclone is used. Some studies have shown that there may be an increased risk of death, and babies sometimes called ‘fetal hydrops’ in the newborn baby. Reduced fetal movement and fetal brain activity may also occur after taking Zopiclone tablets.

During the second and third trimester of pregnancy if Zopiclone tablets are taken then the risk of pregnancy or during labour your baby may have more trouble breathing, a drop in body temperature, difficulty in feeding and breathing problems (respiratory depression). 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 the case the newborn should be closely monitored during the postnatal period.

Breast-feeding

Zopiclone tablets should not be used during breast-feeding unless advised by your doctor.

Fertility

Zopiclone tablets are not recommended for use during breast-feeding if you are breastfeeding, think you may be breastfeeding or planning to breastfeed.

Foetal and breast development

No studies have been performed with Zopiclone tablets in pregnant animals, therefore it is not known whether Zopiclone tablets will have any affect on foetal development or breast development.

Breastfeeding

Zopiclone tablets should not be used during breast-feeding unless advised by your doctor.

Children

Zopiclone tablets should not be used in children.

Menstruation

Zopiclone tablets are not recommended for use during menstruation.
Zopiclone Tablets

Zopiclone 3.75mg & 7.5mg 28 Tablet PIL - UK

Item number: BBBA6491

Originator: R. Paul

Dimensions: 148 x 210mm

Min Body Text Size: 7pt

Supplier: Accord Barnstaple

Pharmacode: 50977653

UK-Eire-Artwork-Support@accord-healthcare.com

FMD info NA (not a carton)

Approved for print/date

Proof Round 2

Technical Approval Date sent: n/a

Date received: n/a

FMD info

* Please note that only Artwork Studio is permitted to make changes to the above artwork.

No changes are permitted by any 3rd party other than added notes and mark ups for required changes.

Version 2 01.11.2017