



**If you take more zolpidem than you should**

If you take more zolpidem 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.

Taking too much zolpidem can be very dangerous. The following effects may happen:

- Feeling drowsy, confused, sleeping deeply and possibly falling into a coma.

**If you forget to take zolpidem**

Zolpidem 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. **Do not** take a double dose to make up for a forgotten tablet.

**If you stop taking zolpidem**

Keep taking zolpidem until your doctor tells you to stop. Do not stop taking zolpidem suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.

If you stop taking zolpidem suddenly, your sleep problems may come back and you may get a ‘withdrawal effect’. If this happens you may get some of the effects listed below.

See a doctor straight away if you get any of the following effects:

- Feeling anxious, shaky, irritable, agitated, or confused
- Feeling restless
- Headache
- Limp or weak muscles
- A lower level of awareness and problems with focusing or concentrating
- Nightmares, seeing or hearing things that are not real (hallucinations)
- Being more sensitive to light, noise and touch than normal
- Relaxed grip on reality
- Numbness and tingling in your hands and feet
- Aching muscles
- Changes in your behaviour
- Fits (seizures)

**4. Possible side effects**

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

**Stop taking zolpidem and see a doctor or go to a hospital straight away if:**

- You have an **allergic reaction**. These signs may include: an itchy, lumpy rash (hives) or nettle rash (urticaria), swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing

**Tell your doctor as soon as possible if you have any of the following side effects:**

**Common side effects (may affect less than 1 in 10 people)**

- Poor memory while taking zolpidem (amnesia) and strange behaviour during this time. This is more likely to affect you in the few hours after you take this medicine. By having 7-8 hours sleep after taking zolpidem 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)

**Uncommon side effects (may affect less than 1 in 100 people)**

- Blurred eyesight or ‘seeing double’

**Rare side effects (may affect less than 1 in 1,000 people)**

- Being less aware of your environment
- Falling, especially in the elderly

**Sleep-driving and other sleep-related behaviour**

There have been some reports of people doing things while asleep that they do not remember when waking up after taking a sleeping medicine. This includes sleep-driving, sleepwalking, preparing and eating food, and having sex. Alcohol and some medicines for depression or anxiety can increase the chance that this serious effect will happen.

**Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:**

**Common side effects (may affect less than 1 in 10 people)**

- Diarrhoea
- Feeling sick (nausea) or being sick (vomiting)
- Abdominal pain
- Respiratory infection
- Headache

- Feeling tired or agitated
- Nightmares
- Depression
- Feeling dizzy
- Feeling sleepy or drowsy
- Back pain

**Uncommon side effects (may affect less than 1 in 100 people)**

- Itching skin or skin rash
- Excessive sweating
- Feeling restless, aggressive, confused or irritable
- Feeling overly happy/confident (euphoric)
- Unusual skin sensations such as numbness, tingling, prickling, burning or creeping on the skin (paraesthesia)
- Tremor
- Sleepwalking (see ‘Sleep-driving and other sleep-related behaviour’)
- Lack of concentration
- Speech problems
- Blurred vision
- Changes in the amount of liver enzymes – shown up in the results of blood tests
- Changes in appetite or behaviour concerning appetite
- Muscle pain
- Muscle spasms
- Limp or weak muscles

**Rare side effects (may affect less than 1 in 1,000 people)**

- Itchy, lumpy rash (urticaria)
- Thinking things that are not true (delusions)
- Changes in sex drive (libido)
- You have discolouration of the skin or eyes, pain in the abdomen (stomach) or a bloated feeling, severe itching, pale or bloody stools, extreme weakness, nausea or loss of appetite. This could be caused by an infection or injury to the liver
- An illness where removal of bile from the liver is blocked (cholestasis). Signs include jaundice, rash or fever and the colour of your water (urine) becomes darker
- Changes in the way you walk

**Very rare side effects (affects less than 1 in 10,000 people)**

- Any changes in vision, in particular loss of vision

- Slower breathing (respiratory depression)
- Becoming dependent on zolpidem

**Not known (frequency cannot be estimated from available data)**

- A feeling of being out of touch with reality and being unable to think or judge clearly (psychosis)
- Feeling angry or showing unusual behaviour
- Needing to take more zolpidem in order to sleep

**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 the Yellow card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 zolpidem**

Keep this medicine out of the sight and reach of children.

Do not use zolpidem after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Store in a dry place below 30°C in the original packaging.

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 Zolpidem 5mg and 10mg Tablets contain**

Each 5mg tablet contains 5mg of zolpidem tartrate as the active substance. Each 10mg tablet contains 10mg zolpidem tartrate as the active substance. The other ingredients of Zolpidem 5mg Tablets are lactose monohydrate, microcrystalline cellulose, hypromellose, sodium starch glycollate, magnesium stearate, titanium dioxide (E171) and macrogol 400.

The other ingredients of Zolpidem 10mg Tablets are lactose monohydrate, microcrystalline cellulose, hypromellose, sodium starch glycollate, magnesium stearate, macrogol, titanium dioxide (E171), talc and polyvinyl alcohol.

**What Zolpidem 5mg and 10mg Tablets look like and contents of the pack**

Zolpidem 5mg Tablets are round, white to off-white, film-coated tablets.

Zolpidem 10mg Tablets are oval, white to off-white, film-coated tablets, with a score line and SN10 on one side.

Zolpidem 5mg Tablets are supplied in cartons of 28 tablets.

Zolpidem 10mg Tablets are supplied in cartons of 28 tablets.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

Zentiva Pharma UK Limited, 12 New Fetter Lane, London, EC4A 1JP, United Kingdom

Manufacturer

Zentiva k.s., U Kabelovny 130, Dolní Měcholupy, 102 37 Prague 10, Czech Republic

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