

Zaleplon, zolpidem and zopiclone for insomnia

**Understanding NICE guidance –
information for people with insomnia,
their families and carers, and the public**

April 2004



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What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS in England and Wales.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance.

NICE was asked to look at the available evidence on the use of three medicines called zaleplon, zolpidem and zopiclone to treat insomnia. NICE was asked to provide guidance that will help the NHS in England and Wales decide when zaleplon, zolpidem and zopiclone should be used.

What is insomnia?

Insomnia is the disturbance of a normal sleep pattern. People with insomnia may find it difficult to get to sleep, or may wake up frequently during the night and have difficulty getting back to sleep, or they may wake very early in the morning. Insomnia can be distressing and may cause problems during the day, such as tiredness, lack of energy, difficulty concentrating and irritability. It may even lead to mental health problems such as anxiety.

Sleep needs vary between individuals. Most healthy adults sleep between 7 and 9 hours per night. There may also be variation from night to night for any one person.

There are many causes of insomnia. A major cause is stress or anxiety and usually the sleep problem disappears when the stressful situation passes. Drinking coffee or alcohol before bedtime may cause sleeplessness. Other causes include medical problems or the use of certain medicines.

If someone has another illness or condition that may be causing insomnia, treating that illness or condition may relieve the insomnia.

There are ways of treating insomnia that do not involve the use of medicines to help people sleep – for example, having regular sleeping hours, avoiding drinking alcohol or coffee at bedtime, and sleeping in a comfortable bed in a room at a comfortable temperature. Other treatments that do not use medicines include a form of psychotherapy called cognitive behavioural therapy and relaxation techniques.

What are zaleplon, zolpidem and zopiclone?

A medicine used to help you sleep is called a hypnotic; these medicines relieve symptoms but do not treat the cause of sleeplessness. Zaleplon, zolpidem and zopiclone are hypnotic medicines used to treat insomnia.

Other hypnotic medicines include a group called benzodiazepines. Some medicines in this group that have effects that do not last as long as other benzodiazepines are called ‘shorter-acting benzodiazepines’.

All hypnotic medicines should be used for short periods of time only. This is because people can become tolerant to their effects and they can cause dependence if they are used for long periods of time. Dependence is an unwanted effect of long-term treatment meaning that

people suffer unpleasant effects when they stop taking the medicines. These effects include anxiety and even panic attacks and people find it impossible to sleep without the treatment.

What has NICE recommended on zaleplon, zolpidem and zopiclone for insomnia?

During the appraisal, NICE's Appraisal Committee read and heard evidence from:

- studies of zaleplon, zolpidem and zopiclone
- doctors with specialist knowledge of insomnia and its treatment
- individuals with specialist knowledge of the issues affecting people with insomnia
- organisations representing the views of people who will be affected by the guidance (because they have, or care for someone with, the condition or because they work in the NHS and are involved in providing care for people with the condition).

The evidence is summarised in the full guidance (see page 10 for details). More information about the studies is provided in the assessment report for this appraisal (see page 10 for details).

NICE has made the following recommendations about the use of zaleplon, zolpidem and zopiclone to treat insomnia within the NHS in England and Wales.

- NICE recommends that doctors should consider using non-medicine treatments, and then, if they think that a hypnotic medicine is the appropriate way to treat severe insomnia that is interfering with normal daily life, they should prescribe one for only short periods of time and strictly according to the licence for the drug.
- Because there is no firm evidence of differences in the effects of zaleplon, zolpidem, zopiclone and the shorter-acting benzodiazepines, NICE recommends that doctors should prescribe the cheapest drug, taking into account the daily dose required and the cost for each dose.
- Treatment should only be changed from one of these hypnotics to another if side effects occur that are directly related to the medicine.
- If treatment with one of these hypnotic medicines does not work, the doctor should not prescribe one of the others.

What should I do next?

If you or someone you care for has insomnia, you should discuss this guidance with your doctor.

Will NICE review its guidance?

Yes. The guidance will be reviewed in April 2007.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on *Zaleplon, zolpidem and zopiclone for the short-term management of insomnia* that has been issued to the NHS. The assessment report, which contains details of the studies that were looked at, is also available from the NICE website. A short version of the guidance (a 'quick reference guide') is available on the website and from the NHS Response Line (reference number N0545).



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