

**Insomnia Formulary Guidance [v3.0]**

**(adapted from NICE guidelines TA77, NG215 and NICE Clinical Knowledge Summary (CKS) - Insomnia Management)**

1. **Introduction**

These guidelines are intended for routine use. However, there will be instances where they are not suitable for the patient you are managing, where more bespoke treatment will be necessary. In such instances the rationale for prescribing away from formulary must be recorded.

Insomnia is difficulty in getting to sleep, difficulty staying asleep, early wakening, or non-restorative sleep despite adequate time and opportunity to sleep, resulting in impaired daytime functioning, e.g. poor concentration, mood disturbance, and daytime tiredness. Insomnia can be classified as follows, according to cause:

* Transient insomnia may occur in those who normally sleep well and may be due to an alteration in the conditions that surround sleeping eg noise, or secondary to workpatterns changing, travel. It may also be associated with acute conditions, often lasting on 1 – 4 weeks.
* Primary insomnia is insomnia that occurs when no co morbidity is identified. Commonly the person has conditioned or learned sleep difficulties, with or without heightened arousal in bed.
* Secondary or chronic insomnia occurs as a symptom of, or is associated with, other conditions, including medical or psychiatric illness, or substance misuse. Often this can be long term in nature

1. **Non- Pharmacological Treatment – Key Points**

Management of insomnia requires resolution of any stressful precipitant or identification and treatment of underlying causes. Prescribers should routinely provide information on promotion of good sleep habits (sleep hygiene) to make people aware of behavioural, environmental, and temporal factors that may be detrimental or beneficial to sleep.

General tips to help with sleep include:

* Treat/Manage any underlying conditions which may be causing the sleep disturbance e.g., pain
* Establish fixed times for going to bed and waking up (never sleep in the day and avoid sleeping in after a poor night’s sleep)
* Try to relax before going to bed – warm drink, hot bath, reading or a relaxation tape may help
* Maintain a comfortable sleeping environment: not too hot, cold, noisy or bright.
* Avoid stimulants such as caffeine and nicotine in the evening. (Consider complete elimination of caffeine from the diet, but be aware of withdrawal effects)
* Avoid exercise within 4 hours of bedtime (although exercise earlier in the day is beneficial.)
* Avoid eating a heavy meal late at night

1. **Pharmacological Treatment – Key Points**

**General Principles**

Whenever hypnotics are prescribed the risks must be discussed with the patient or representative, including likely benefits, risks, including the development of tolerance and dependence, falls, confusion. This should be made available in a format appropriate for the patient.

When stopping hypnotics then the duration of prescription should be taken into account to avoid the risk of withdrawal symptoms, balanced against the risks of continuing. Clear information on the likely duration of the prescription must be given.

NICE do not recommend hypnotics for chronic insomnia (Greater than 3 months duration)

**Inpatient Use**

* If following review, a new prescription is required, this should be time limited, with a review/stop date added (initially a maximum of one week)
* Out of hours hypnotics should not normally be prescribed. In the exceptional circumstances where it is necessary, the prescribing should be done as ‘Administer Once Only’ to allow it to be reviewed by the day team.
* Patients going on leave/discharge should have their hypnotics reviewed, especially any when required prescriptions, and only continued if required. A plan should be included in the discharge letter to the GP.
* Patients admitted taking hypnotics should have them reviewed, and where possible a plan to slowly phase them out agreed.

3.1. Hypnotics

* There is good evidence for the efficacy of hypnotic drugs in short-term insomnia, but they do not treat any underlying cause.
* Their use is associated with adverse effects, such as daytime sedation, poor motor concentration and cognitive impairment. In older people, in particular, the magnitude of the beneficial effect of hypnotics may not justify the increased risk of adverse effects (i.e., falls and cognitive impairment).
* Non-pharmacological measures should be considered before prescribing hypnotics.
* Hypnotic medication should only be initiated when non-pharmacological interventions have been unsuccessful for managing severe insomnia and after discussion with the service user.
* Hypnotics should be prescribed at the lowest effective dose for as short a period as possible, in strict accordance with their licensed indications.
* In transient insomnia, one or two doses of a short-acting hypnotic may be indicated, whereas in short term insomnia intermittent dosing of a short acting hypnotic given for no more than 3 weeks may be appropriate. Chronic insomnia rarely benefits from the routine use of hypnotics and should where possible be avoided. Tolerance develops quickly (3 – 14 days continuous use), and withdrawal after long term use, can lead to rebound insomnia and other withdrawal problems.
* A number of hypnotic drugs are licensed for the treatment of insomnia, including the benzodiazepines (temazepam) and Z-drugs (zopiclone, zolpidem)
* Benzodiazepines are effective but many people develop tolerance to their effects, gain little therapeutic benefit from chronic use, and become both physically and psychologically dependant on them after 2-4 weeks of regular use.
* A withdrawal syndrome (anxiety, depression, nausea and perceptual changes) which may be prolonged is associated with discontinuation. This can lead to insomnia which is worse than the original symptoms.
* Due to problems with misuse, benzodiazepines should be avoided in patients with a history of substance misuse. The MHRA advise that they should only be used to treat insomnia only when it is severe, disabling or subjecting the individual to extreme distress. The lowest dose should be used and should not continue beyond four weeks.

3.2. The ‘Z drugs’

* Zolpidem and zopiclone (the Z-drugs) are non-benzodiazepine hypnotics. They differ structurally from the benzodiazepines.
* Manufacturer summaries of product characteristics (SPCs) state: long-term continuous use is not recommended; a course of treatment should not exceed four weeks during a single period. The SPC’s carry a warning of the potential to cause dependence, tolerance, and withdrawal symptoms
* NICE guidance is available on Zolpidem, and zopiclone in the short term
* Management of insomnia (NICE TA77, April 2004). Key points are:
  + After careful consideration of non-pharmacological measures, hypnotic drug therapy may be considered appropriate, but should be prescribed for short periods of time only, in line with their licence.
  + Due to lack of compelling evidence to distinguish between the z-hypnotics, the drug with the lowest acquisition cost should be prescribed.
  + Switching between these hypnotics should only occur if the service user experiences adverse effects considered to be directly linked to the agent used.
  + Service users who have not responded to one of these hypnotic drugs should not be prescribed any of the others.

3.3. Melatonin for Sleep disorders in children

Inpatients with ADHD and Autism Spectrum disorder with significant sleep disorder Melatonin may be considered as a treatment option.

The medication of choice is Circadin 2mg MR tablets, this is an off-label use of this medication, and this must be documented and discussed with the patient/carer. Written information should be given to the patient/carer. It can be crushed when immediate release melatonin is required.

**Potential indications and advice:**

* Severe sleep disorders in neurodevelopmental or psychiatric disorders.
* Behavioural strategies have had limited or no success.
* Significant adverse effects on the child / family prior to work by an appropriate agency (see below).
* Short term use (6 months)
* To aid work on sleep hygiene by health visitor, nursery nurse, school nurse,

A small number of children may need Circadin® long term, reviewed every 12 months

**Guidance:**

**Dose**

Start at 2mg given before going to bed. Crushed tablets are given 30 minutes before bed and whole tablets are given an hour before bedtime. Increase, if necessary, after 1 - 2 weeks by 2mg to a maximum of 10mg.

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| Sleep Initiation | Use Circadin® tablets crushed (to render it standard release) and mixed with clear fluids, juice, milk or e.g., yoghurt.-. |
| Early Morning wakening and sleep maintenance | Use Circadin® tablets swallowed whole. |
| Mixed | Some children need a combination of standard release and modified release properties. Use Circadin® in a mixture of whole and crushed forms with maximum combined dose of 10mg. |

**Interactions and Side effects**

See current SPC for full information on interactions and side effects

<https://www.medicines.org.uk/emc/product/2809>

**Monitoring:**

Response to treatment.

Monitoring of growth and sexual development with long term use is primarily the responsibility of the child’s consultant but the GP should report any concerns.

Long term effects have not been fully evaluated in humans but observations from animal models regarding the effect on pituitary hormones necessitate precautionary monitoring.

Ensure a drug holiday of 7 days every 6 months has been undertaken and that the sleep diary has been completed to reflect this.

Where shared care exists, this should be followed, this can be found on the CCG website

[Rotherham Shared Care](http://www.rotherhamccg.nhs.uk/Melatonin%20Shared%20Care%20Protocol%20TRFT%20RCCG%20Feb%202018%20V%201%200%20EMM%20amended%20RMOG%20V2.pdf)

[Doncaster Shared Care](http://medicinesmanagement.doncasterccg.nhs.uk/documents/melatonin/)

3.4. Melatonin in adults over 55 ([NICE CKS Chronic Insomnia](https://cks.nice.org.uk/topics/insomnia/management/))

* For people over 55 years of age with persistent insomnia, treatment with a modified-release melatonin may be considered.
  + The recommended initial duration of treatment is 3 weeks. If there is a response to treatment, continue for a further 10 weeks only.
  + Discuss the risks (similar to those of other hypnotics including falls, and fractures) associated with melatonin treatment in the elderly.

1. **References**
2. NICE (2004) Guidance on the use of zaleplon, zolpidem and zopiclone for the short- term management of insomnia: Technology Appraisal 77 <http://guidance.nice.org.uk/TA77>
3. NICE Clinical Knowledge Summary [CKS NICE](https://cks.nice.org.uk/topics/insomnia/management/)
4. SPC [www.emc.medicines.org.uk](http://www.emc.medicines.org.uk)
5. BNF 84th eds. Available online at: <http://www.bnf.org>

**Table 1: PHARMACOLOGICAL TREATMENTS FOR INSOMNIA**

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| **First Line:** | **Relative Cost** | **Notes** |
| Zopiclone | £ | 3.75-7.5mg at bedtime when required.  Older adults and hepatic and renal impairment - 3.75mg tablet at night when required  Use for a short period of time only in strict accordance with the licensed indications  Non-pharmacological measures should be considered before drug therapy for insomnia. |
| **Second Line:** | **Relative Cost** | **Notes** |
| Zolpidem | £ | 5-10mg at night when required;  Older adults and hepatic and renal impairment: 5mg at night when required  The only acceptable reason to change hypnotics should be intolerance to the current drug. |
| Temazepam | ££ | 10mg at night when required; Scheduled 3 controlled drug. Subject to storage, prescribing and  record-keeping requirements.  To be used if Z-drugs are not suitable or tolerated.  Not to be used if there is history of substance misuse due to risk of dependence and tolerance. |
| **Not Recommended** | **Relative Cost** | **Notes** |
| Antihistamines  Antidepressants  Antipsychotics  Long-acting  Benzodiazepines (including Nitrazepam)  Clomethiazole  Chloral hydrate  Melatonin MR | £  £-£££  £-£££  £  ££  ££  £££ | Use of these agents for their sedative effects is not supported by evidence.  Potential for side effects such as daytime sedation, cognitive impairment and falls is significant.  Antihistamine may cause troublesome antimuscarinic effects  Benzodiazepines with longer half-lives may cause hangover effects;  \*  \* licensed for >55yrs. Exception for CAMHS |

**TABLE 2: DRUG SPECIFIC INFORMATION**

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| **Hypnotic drug** | **License** | **Cautions** | **Key side-effects** |
| Zopiclone | Short term treatment of insomnia, transient,  situational or chronic insomnia and insomnia  where the insomnia is debilitating or is causing  severe distress for the patient. **Duration of**  **treatment should not usually vary from a few**  **days to 2 weeks**with a maximum of 4 weeks. | Use lower doses in renal/hepatic  impairment and older adults  Avoid in severe hepatic  impairment and respiratory  insufficiency | Bitter or metallic taste; nausea,  dizziness, drowsiness, dry mouth,  nightmares, rarely lightheadedness,  confusion and ataxia |
| Zolpidem | Short term treatment of insomnia where the  insomnia is debilitating or causing severe  distress. **Duration of treatment should usually**  **vary from a few days to 2 weeks** with a  maximum of 4 weeks. | Use lower doses in renal/hepatic  impairment and older adults  Avoid in severe hepatic  impairment and respiratory  insufficiency | Diarrhoea, nausea, vomiting,  dizziness, headache, drowsiness,  fatigue, confusion, agitation,  nightmares, amnesia; ataxia, falls,  sleep walking |
| Temazepam | Short term treatment of insomnia – up to 4  weeks. Treatment should be at the lowest dose  possible. | Caution in renal/hepatic  impairment use low doses and  avoid in severe hepatic  impairment. | Drowsiness, light headedness the  next day, confusion and ataxia  (elderly), amnesia and dependence. |
| Melatonin | Patients aged over 55, as monotherapy for up  to 13 weeks for primary insomnia.  Consider in CAMHS patients with ASD or ADHD (off label) | Not recommended in  hepatic/renal impairment  Alcohol- reduces effect of  melatonin on sleep. | Abdominal pain, dyspepsia,  irritability, dizziness, dry mouth,  migraines, constipation, stomach  pain and weight gain. |