NON-PRESCRIPTION SLEEP AIDS

FIXING YOUR ZZZ IN THE PHARMACY

CASE SCENARIO

Amna, 26 years old, is browsing the vitamins and herbal supplements section of the pharmacy, seeking a solution for her sleep problems. Over the past 2 weeks, she has experienced difficulty falling asleep at night and feels exhausted when she wakes up at 7 am to get ready for work. She also wants some information about melatonin, as some of her older colleagues have had success with it. Amna is an otherwise healthy young adult without co-existing medical comorbidities and is not currently taking any other medicines.

Introduction

Non-prescription sleep aids are frequently purchased by individuals to improve their sleep while delaying seeking medical care.[1] Given the product availability and proximity of community pharmacy to the public, the pharmacist has an important role to play in promoting the safe and effective use of non-prescription sleep aids and referring patients to appropriate care.[2,3]

Common non-prescription sleep aids

Non-prescription sleep aids predominantly target insomnia symptoms, utilising their sedative properties to promote faster sleep onset. These are mainly Schedule 3 medicines and include the sedating antihistamines diphenhydramine, promethazine and doxylamine.[4] Prolonged-release melatonin may be used as a Schedule 3 medicine in adults ≥55 years of age as a short-term monotherapy for primary insomnia, characterised by poor sleep quality.[4] »

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OUR AUTHOR

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CONFLICT OF INTEREST DECLARATION

Dr Cheung supervises a PhD candidate on a project exploring treatment experiences and needs of self-identified Chinese patients in Australia. The candidate is employed by ResMed Pty Ltd and the company directly funds the research candidate's research project costs as part of a professional development fund. The funding and nature of the project is not related to this CPD activity.

LEARNING OBJECTIVES

After reading this article, pharmacists should be able to:

- Discuss examples of non-prescription management options for sleep disturbance
- Discuss risks of using non-prescription sleep aids to manage sleep disturbance
- Explain the role of the pharmacist in assisting patients who request medicine to aid sleep disturbance.

Competency standards (2016) addressed: 1.1, 1.4, 1.5, 2.2, 3.1, 3.5

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Complementary medicines (CMs; e.g. valerian, passionflower, hops, kava, chamomile) and supplements (e.g. magnesium) are also sometimes used to help aid sleep.[5,6] Many of the CMs theoretically act on GABAergic receptors and/or have anxiolytic and relaxant effects.[7] The *Australian Pharmaceutical Formulary and Handbook* contains further information on various CMs and their reported uses in sleep.[6]

A key practice dilemma that pharmacists face each day is that despite the widespread availability and use of non-prescription sleep aids, several professional sleep societies recommend against their use due to insufficient evidence.[8–10] *Therapeutic Guidelines* also advises not to use sedating antihistamines to treat insomnia.[11] Many of the pivotal trials evaluating first-generation sedating antihistamines and CMs have critical study design limitations that fall short of the *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) standards that are often used to appraise the evidence base.[12]

While the evidence bases for both CMs and Schedule 3 sleep aids are unlikely to immediately change, a core practice consideration is the risk-benefit profile of the respective non-prescription sleep aids for the individual patient.

Risks of self-medication with non-prescription sleep aids

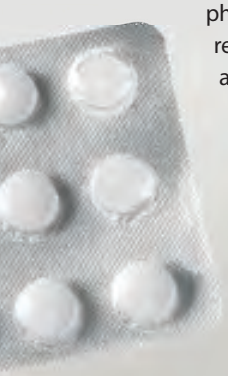
Consumers often misperceive non-prescription sleep aids as being safer than prescription medicines due to their 'naturalness' or ease of access.[13] As such, these sleep aids are often used medically unsupervised to either initially delay seeking medical care,[14] or, in combination with prescribed regimens, to offset the perceived harms of prescription sleep aids.[15,16] When non-prescription sleep aids are being used unsupervised, consumers may be unaware of the potential contraindications or interactions with existing medicines. For example, melatonin, while seemingly benign, can have undesired effects in high-risk patient groups. Melatonin can potentially interfere with immunosuppressive therapies,[17] and may increase risk of bleeding for patients on anticoagulant medicines such as warfarin.[18,19] While many of the interactions with CMs are theoretical, pharmacists play a critical role in assessing risk-benefit and providing advice for the safe use of these non-prescription sleep aids. Nonetheless, discerning the risk profiles of the respective CMs is increasingly challenging since many herbal sleep formulations in the pharmacy combine multiple herbal ingredients.

Patients should be advised to avoid the concomitant use of non-prescription sleep aids with alcohol and medicines that have central nervous system depressing effects, and to avoid driving or operating machinery if drowsy.[20] The effects of sleep aids, especially sedating antihistamines, can continue the next day.[4,20,21] In addition, non-prescription sleep aids should be limited to short-term use. Sedating antihistamines should not be used for longer than 10 consecutive days because tolerance to their sedative effects develops quickly.[4,21,22] In older adults, the risks of using non-prescription sleep aids are even higher. This is because they tend to take more medicines, increasing the potential for drug-drug and drug-herb interactions. In addition, the sedative effects of sedating antihistamines may be more pronounced due to age-related pharmacokinetic and pharmacodynamic changes, such as reduced metabolism and clearance.[23] Older adults are also more vulnerable to other cognitive

and anticholinergic adverse effects of sedating antihistamines, and these medicines can add to the anticholinergic burden.[21] Guidelines recommend avoiding the use of sedating antihistamines in older people.[4] However, older people make up a significant portion of users.[23] If it is not possible to avoid use in older people, they should use lower doses than other adults.[21]

Notwithstanding these acute consequences, one of the main concerns of self-medication is delayed medical help-seeking and initiation of the first-line therapy, cognitive behavioural therapy for insomnia (CBTi).[24] Individuals may miss the optimal window to address their sleep complaint and allow perpetuating factors such as poor sleep habits and anxiety about the lack of sleep to develop, resulting in the transition of acute insomnia into chronic insomnia (insomnia lasting ≥3 months).[8]

Is it really insomnia?



From direct product requests to symptom-based requests in the pharmacy, patients will often refer to their sleep complaint as 'insomnia' and seek non-prescription sleep aids to improve their sleep. Insomnia symptoms such as difficulty initiating sleep, maintaining sleep, early-morning waking and associated daytime fatigue can appear to overlap with symptoms of other sleep disorders for which non-prescription sleep aids may not be suitable. For example, circadian sleep disorders such as advanced sleep phase disorder and delayed sleep phase disorder share a lot of similarity with insomnia symptoms where the patient experiences difficulty falling asleep at a desired time.[25,26] Those with a circadian sleep disorder have an otherwise intact sleep-wake cycle but struggle to fall asleep and wake up at socially acceptable times to meet their daily obligations such as work and school because their internal body clocks have shifted.[10] Similarly, for patients with undiagnosed obstructive sleep apnoea (OSA), the daytime fatigue and functional impairments often motivates patients to use non-prescription sleep aids to improve their sleep or alertness, but clinical guidelines recommend against their use.[27] Another common sleep disorder, restless legs syndrome (RLS), like insomnia, will result in difficulty falling asleep and/or staying asleep with daytime consequences. The disrupted sleep in RLS is largely attributed to the uncomfortable sensation felt in the legs at night when resting and the urge to move and stretch out the legs to relieve discomfort.[28] The symptoms of RLS can be precipitated or exacerbated with use of sedating antihistamines.[29] »

Further clinician and patient information on these conditions can be obtained from Sleep Central (*www.sleepcentral.org.au*), or consumer-facing resources from the Sleep Health Foundation (*www.sleephealthfoundation.org.au*).

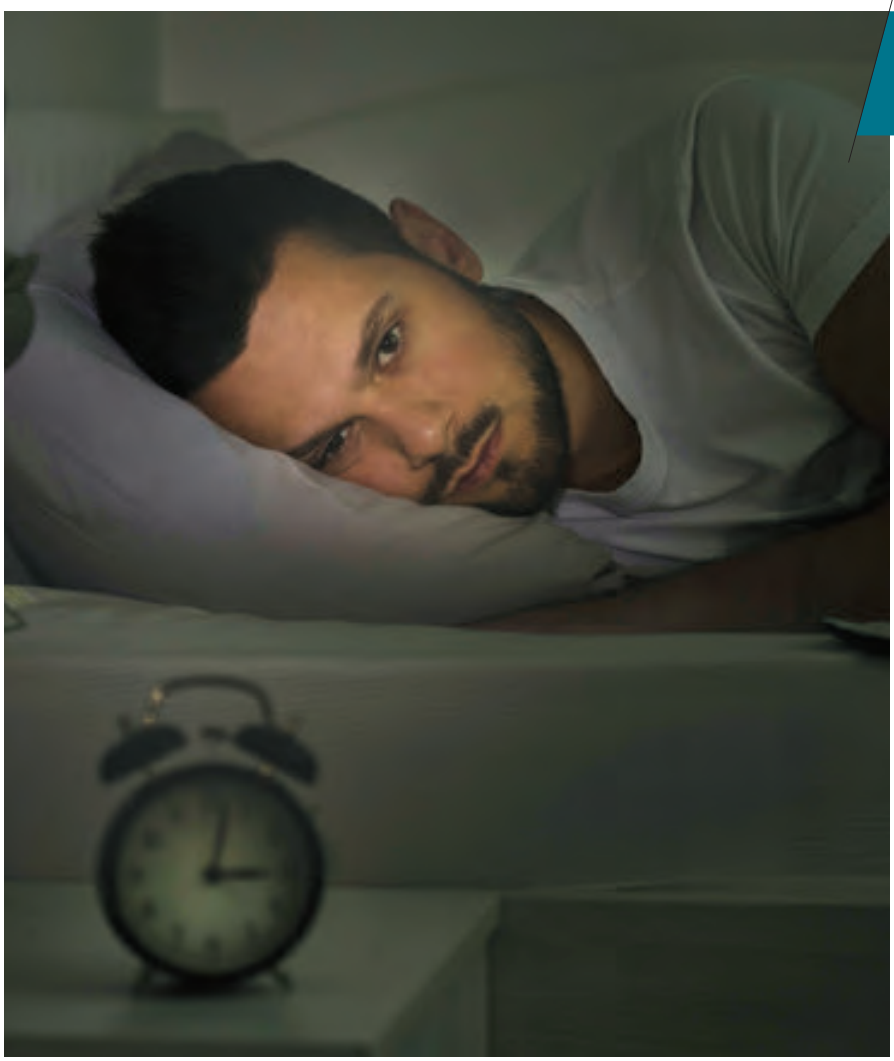
The role of the pharmacist

Patients presenting to the pharmacy for non-prescription sleep aids should be assessed for the presence of other sleep disorders.[30,31] Pharmacists can probe further into the nature and history of the sleep complaint by asking patients about potential triggers, sleep-wake schedules, engagement in shift work, the presence of other physical symptoms (e.g. snoring or witnessed breathing pauses during sleep, uncomfortable sensations in the lower legs and ability to fall asleep easily at earlier/later times), and prior treatments and response to treatments.[3] In addition, there are evidence-based screening and assessment tools for the different sleep disorders that pharmacists may use in their practice to identify at-risk patients for onward referral and assessment by their medical practitioner.

Further information on assessment tools for insomnia and patient education resources can be found on the Sleep Central website (*www.sleepcentral.org.au*).

Knowledge to practice

Despite insufficient evidence supporting the use of non-prescription sleep aids, it is critical to engage patients in a non-judgemental and open discussion about their non-prescription sleep aid use.[32] Through these conversations, pharmacists can gain further information about the nature of the patient's sleep complaint, their current medical and medicines history and treatment expectations. Pharmacists can then educate patients about the various sleep disorders, potential adverse effects and interactions of pharmacological treatment, and inform them about the benefits of seeing a medical practitioner for assessment and optimal treatment.



Conclusion

Non-prescription sleep aids are widely used by members of the community to improve their sleep, but they may not always be an appropriate choice, and risks can often outweigh perceived benefits. Pharmacists play a key role in ensuring non-prescription sleep aids are used safely and effectively. Pharmacists are well placed to direct consumers to evidence-based resources on sleep health and sleep disorders, which may empower them to be better informed about sleep, improve their sleep health literacy, and understand the need for further assessment from a medical practitioner. They can also facilitate onward referral to a medical practitioner for further assessment, differential diagnosis and management of their sleep disturbance.

CASE SCENARIO CONTINUED

You ask Amna about her sleep. She wants to go to sleep by 10:30 pm but typically doesn't feel sleepy until 1 am. Her sleep complaint is only an issue on weekdays when she needs to follow a strict schedule. Weekends are pleasant as she can sleep and wake when she wants. You suggest that Amna may have symptoms of a delayed circadian rhythm rather than insomnia, and refer her to see her GP for a discussion and referral to a sleep specialist. »

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KEY POINTS

- **Non-prescription sleep aids are commonly sought by patients experiencing sleep complaints in the community.**
- **Pharmacists are well positioned to discuss with patients the risk-benefit profiles of non-prescription sleep aids when assessing their suitability for individual patients for short-term use.**
- **Presenting symptoms of different sleep disorders often overlap with insomnia symptoms.**
- **Pharmacists play a key role in screening patients at risk of sleep disorders and referring them to evidence-based resources and appropriate care.** AP

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ASSESSMENT QUESTIONS

Each question has only one correct answer.

1 **Which ONE of the following options is correct regarding non-prescription management options for sleep disturbance?**

A Melatonin is available as a Schedule 3 medicine for adults aged 55 years and older with secondary insomnia.

B Examples of complementary medicines sometimes used to help aid sleep include passionflower and valerian.

C Professional sleep organisations recommend sedating antihistamines first-line to treat insomnia due to their lower risk profile.

D Examples of Schedule 3 medicines for insomnia include doxylamine, promethazine and immediate-release melatonin.

2 **Which ONE of the following options is *CORRECT* regarding use of non-prescription sleep aids to manage sleep disturbance?**

A Melatonin is the first-line pharmacological treatment for insomnia in adults aged ≤55 years.

B Age-related changes in pharmacokinetics and pharmacodynamics can produce more pronounced adverse effects in older patients using sedating antihistamines.

C Sedating antihistamines are the recommended pharmacological treatment option for older patients experiencing insomnia.

D For patients with suspected insomnia, sedating antihistamines are a safe and effective way to manage the condition long-term.

3 **Alex is a 42-year-old patient who has been having trouble sleeping at night for the past 12 weeks after a relationship breakup. They are not currently on other medicines. They saw online that melatonin is effective in helping aid sleep. Which option is *MOST* appropriate in assisting Alex?**

A Ask Alex more about the nature of their sleep problems, supply prolonged-release melatonin, and refer to the doctor for further assessment.

B Ask Alex more about the nature of their sleep problems, discuss the option of completing an evidence-based screening and assessment tool, and refer to the GP for further review and assessment.

C Ask Alex to complete an evidence-based assessment tool to see if they have a sleep disorder. If the tool indicates insomnia, provide them with a sedating antihistamine, such as doxylamine, to try for a couple of weeks.

D Advise Alex that sedating antihistamines would be more appropriate to help manage their symptoms.

4 **Which ONE of the following options is *CORRECT*?**

A There is strong evidence supporting the use of non-prescription sleep aids for insomnia.

B Non-sedating antihistamines may be used longer term in those with insomnia, as they don't induce tolerance.

C Pharmacists may use evidence-based screening tools to help identify at-risk patients for further referral or assessment.

D Sedating antihistamines may relieve symptoms of restless legs syndrome.