

Idorsia

Targeting overactive wake signals in long-term insomnia – a closer look at QUVIVIQ™ ▼ (daridorexant)



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Intended for UK healthcare professionals only. Prescribing information for QUVIVIQ™ and adverse event reporting information can be found by scanning the QR code or by visiting <https://prescribing-information-quviviq.idorsia.uk/>



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Foreword

Abbreviations

BZ	Benzodiazepines	IDSIQ	Insomnia Daytime Symptoms and Impacts Questionnaire
CBTi	Cognitive behavioural therapy for insomnia	LPS	Latency to persistent sleep
DORA	Dual orexin receptor antagonist	NICE	National Institute for Health and Care Excellence
DSM-5	Diagnostic and Statistical Manual of the American Psychiatric Association	PSG	Polysomnography
GABA	Gamma-aminobutyric acid	SMC	Scottish Medicines Consortium
GP	General practitioner	WASO	Wakefulness after sleep onset
ICD-11	International Classification of Diseases		



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Helping patients sleep well and live well: the importance of treating insomnia

General practice has never been more challenging. Record-breaking numbers of GP consultations, complex multimorbidity, and increasing administrative demands mean that sleep problems can easily be pushed down the priority list.¹ Many of us were never properly taught how to recognise or treat insomnia during our training; doctors receive a median of **<2 hours of sleep medicine education**, and this is almost entirely focused on obstructive sleep apnoea.²

As a GP with a special interest in sleep medicine, I understand these pressures firsthand. I also know how tempting it can be to view sleep difficulties as secondary issues, overshadowed by more urgent clinical concerns.

Chronic insomnia is not merely an inconvenience; it is a recognised disorder in its own right, carrying increased risks of diabetes, cardiovascular disease, depression, and even suicidality when left untreated.³ Ignoring it may seem like a time-saving decision in the short term, but it is, in truth, a false economy.⁴ Patients with untreated insomnia are more likely to reattend, have worse control of chronic diseases,⁵ and experience more frequent emergency admissions.

Untreated insomnia extends its effects far beyond tiredness.⁶ It drives a 24-hour pattern of dysfunction and dysregulation that touches every aspect of a patient's life, impairing concentration, memory, mood, and physical stamina.⁷ Relationships, work, and overall quality of life suffer – often invisibly, until the burden becomes overwhelming.⁶

Our understanding of insomnia has evolved significantly in recent years. No longer considered merely a

symptom of other conditions, insomnia is now recognised as a disorder in its own right.⁸ Both the DSM-5 and the ICD-11^{8,9} classifications reflect this shift, encouraging clinicians to diagnose and treat insomnia independently, rather than viewing it as secondary to other problems.⁸

In my opinion, this reframing is vital. It empowers us, as GPs, to take insomnia seriously and to intervene earlier, preventing the cascade of physical and psychological complications that so often follow when sleep disturbance is left unchecked. Crucially, it also gives our patients permission to see their sleep difficulties as valid health concerns, worthy of treatment and attention.

In a busy primary care setting, time is always at a premium.¹ Yet simply asking patients about their sleep – and recognising when sleep difficulties may be contributing to other health problems – is a powerful first step. When sleep issues are identified, **offering a separate appointment to focus fully on them can make all the difference.**⁴

Giving insomnia the time and space it deserves may feel like a luxury, but it can prevent far greater demands on our time later.¹⁰ Patients who sleep better manage their physical and mental health better too,⁸ making every aspect of their care more straightforward.

Until now, many of us have been left to muddle through with little formal training or clear guidance,² and only a handful of medication options not suited to manage insomnia of long-term nature. This handbook pulls together various elements

of guidance, offering us support in the structured, evidence-based approach to treating insomnia appropriately, confidently, and compassionately.

We now have access to treatments that not only improve sleep, but also do so in a way that preserves normal sleep architecture and improves daytime functioning.¹¹ By giving sleep the attention it deserves, we can make a meaningful difference – not just to how our patients feel at night, but to how they live each day.

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Introduction

Insomnia, the most common sleep-wake disorder,¹ can be defined as “a sleep disorder characterised by difficulty falling asleep, staying asleep, early waking, or a combination of these symptoms” with sleeping troubles causing “daytime impairments, such as sleepiness or difficulty concentrating.”² (Fig. 1)

Sleep is vital for physical and mental health,¹ **not getting enough sleep or poor quality sleep can impact daily functioning**, which can be debilitating.²

Insomnia is no longer considered a symptom of another disorder and is acknowledged as a condition in its own right.⁴ Chronic insomnia, or long-term insomnia, is characterised by difficulties sleeping and related daytime symptoms

Risks associated with persistent insomnia:³

- Increased risk of diabetes
- Increased risk of cardiovascular disease
- Increased risk of suicide

on at least three days per week for longer than three months.²

What factors influence the development and maintenance of long-term insomnia? The “3P” model

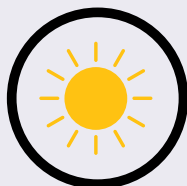
The most well-known model for studying insomnia is the 3P model, conceptualised by AJ Spielman et al (Fig. 2). Within this model, the three Ps (predisposing,

Figure 1: Nighttime and daytime symptoms of insomnia



One or more nighttime symptoms:²

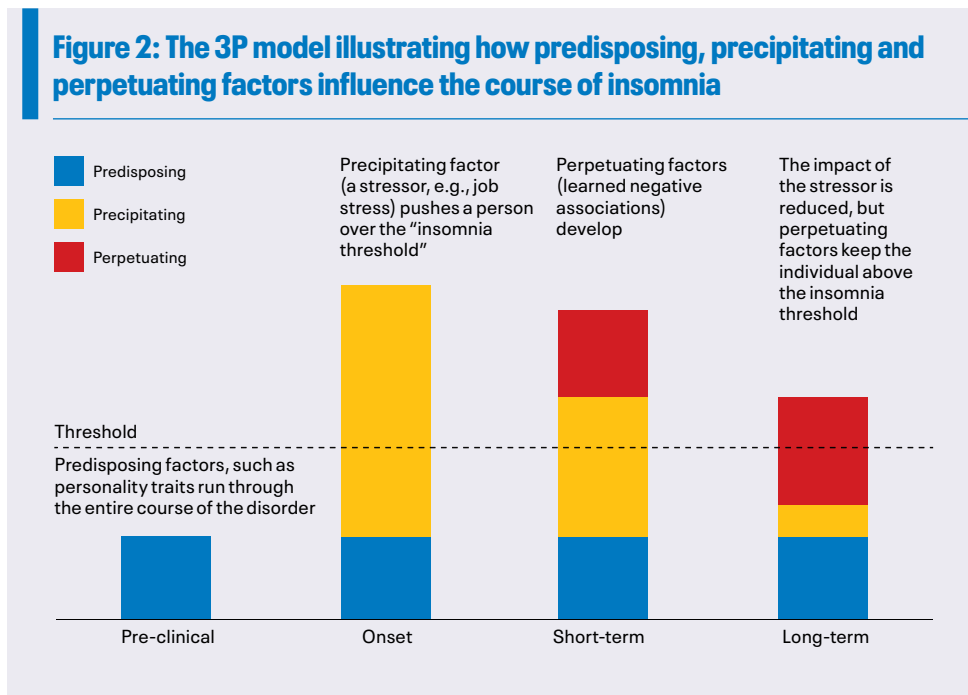
- Trouble falling asleep
- Trouble staying asleep
- Early waking



Daytime symptoms may include:⁴

- Fatigue
- Cognitive impairment
- Depressed mood
- General malaise
- Distress or impairment in social, occupational, educational, academic, behavioural, or other important areas of functioning

Figure 2: The 3P model illustrating how predisposing, precipitating and perpetuating factors influence the course of insomnia



(adapted from Spielman et al, 1987)⁵

precipitating and perpetuating factors) all impact crossing over the threshold to remain in long-term insomnia.⁵

Predisposing factors can increase the likelihood of disruption to sleep when a stressor is introduced.⁶ These can include:³

- Personality characteristics, e.g., suppressing emotions
- Genetic factors
- Neurobiological mechanisms, e.g., homeostatic and circadian dysregulation

Precipitating factors, can normally be readily identified and include significant life events, e.g., work-related stress.³

Perpetuating factors e.g., anxiety associated with trouble sleeping or spending longer in bed exacerbate insomnia by developing negative associations and remain long after the precipitating factors subside.⁵

This leads to patients experiencing **long-term** insomnia.

The real-world burden of long-term insomnia: a closer look at its widespread effects

An average of 10% of the European adult population suffers from long-term insomnia.³



Prevalence of long-term insomnia

Females are more commonly affected by long-term insomnia than males (ranging from 60% versus 40% and is thought to be as much as 2–3 times as common),³ and the risk increases with increasing age, family history and environmental stressors.⁷

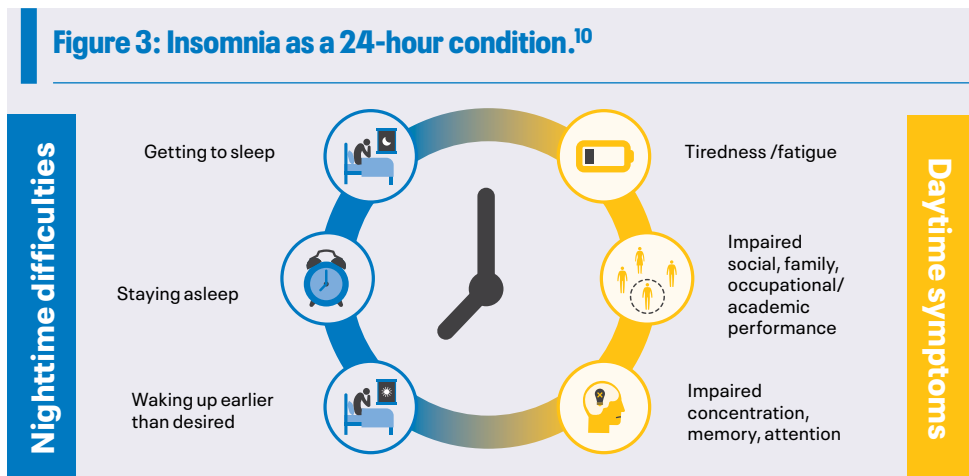
The prevalence of long-term insomnia varies between countries, with recent data indicating an increase in prevalence

in recent years,⁸ and rates as high as 14.8% in the UK.⁹

Nighttime symptoms and daytime symptoms: insomnia is a 24-hour condition¹⁰

Insomnia is a **24-hour condition** (Fig. 3); in addition to nighttime symptoms, insomnia interferes with activities during the day, leading to sleepiness and difficulties concentrating.²

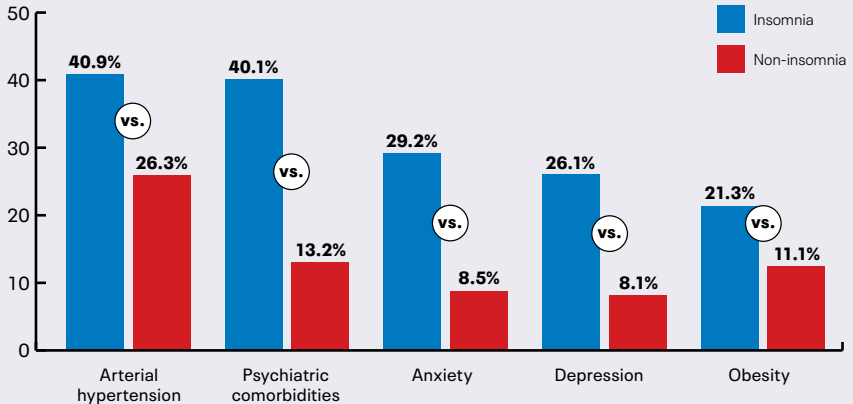
Figure 3: Insomnia as a 24-hour condition.¹⁰



Adapted from Morin CM, et al. *Nature Rev* 2015;1:1-18.

The substantial health burden associated with insomnia

A large-scale study involving approximately 1 million patients found that compared with those with no history of insomnia disorder, patients with untreated insomnia have an increased likelihood of:⁷



Insomnia is often a **persistent** condition; 59.1% of patients continued to suffer from long-term insomnia after 5 years. Owing to the **long-term adverse outcomes** associated with persistent insomnia (Fig. 3), treatment should be initiated **promptly** when sleep disturbances and impact on day-to-day life are reported.¹¹

In addition to the link with chronic health conditions (depression, arterial hypertension, anxiety, etc.),⁷ patients with insomnia have an increased likelihood

of hospital admissions. A large study involving 4,300 adults aged ≥ 65 years in the US found that a diagnosis of insomnia disorder was associated with greater odds of:¹²

- Emergency department visits
- All-cause hospitalisations
- All-cause 30-day readmissions

This was the case even after adjusting for potential confounders, including health and demographic characteristics.¹²




These findings are supported by, and may be explained by, research showing that insomnia disorder leads to increased rates of **dizziness**, increasing the risk of falls and emergency admissions. Patients with untreated insomnia also experience increased levels of **disorientation**, which can be particularly important when considering older adults aged ≥ 65 years.⁷

Sleep therefore has a complex relationship with physical and mental health, and **addressing disturbed sleep can help improve population-level outcomes.**¹²

The link between menopause and insomnia - prevalence and underlying causes

Sleep disturbances can be particularly common during the perimenopause, menopause and post menopause periods.

Between 28 and 63% of women experience sleep disturbance during menopause.¹³



Changes in hormone levels can lead to disturbed sleep. Women who already experience sleep disturbances prior to menopause are at higher risk of menopause-related insomnia,¹⁴ and as sleep disturbances alter hormone levels further, this can turn into a vicious cycle.¹⁵ **Menopause-related insomnia can last for weeks or months if not properly treated.** It can impact all areas of life,¹⁵ and can be an underlying cause of depression and anxiety.¹³

The wide-spread societal and economic impact of insomnia

The impact of insomnia extends far beyond the individual, with ripple effects that can affect families, employers, and

even global economies (Fig. 4).⁹

Productivity loss in the workplace costs the UK economy up to US\$41.4 billion (equivalent to approximately £32 billion) in gross domestic product (GDP) per year.⁹

Figure 4: The societal burden of insomnia⁹

● **Poorer self-rated life satisfaction**

● **Poor physical and mental health-related quality of life**

● **Increased likelihood of absence from work and less productivity whilst at work**

Annually, long-term insomnia was associated with:

11-18
days of absenteeism

39-45
days presenteeism
(at work but less productive)

44-54
days of overall productivity loss annually

● **Increased risk of workplace-related errors and accidents, which lead to injuries and disability**

Insomnia was associated with a **75-88%** increase in likelihood of an accident that led to permanent work disability

Meet Anna, a patient with long-term insomnia



The patient case is fictional and presented for illustrative purposes only.

Patient profile

Anna is a data analyst who enjoys swimming and being outdoors. She has been experiencing difficulties staying asleep, starting 4 months ago when she had an extremely busy period at work.

She tried multiple lifestyle changes, e.g., regular bedtime, dark comfortable room, and staying active during the day. She has found that the insomnia has persisted, even after work calmed down, and is worried that the sleepiness is affecting her work in the day.

Anna has visited her GP a few times for various issues potentially linked to her poor sleep. She noticed that she had always had anxiety, but that this had become much worse in the last 4 months, coinciding with the onset of insomnia. Her daytime fatigue and poor concentration is affecting her relationship with her daughter, and her disruptive night's sleep

often means she leaves the bedroom in the middle of the night to avoid disturbing her husband. Her GP started her on a selective serotonin reuptake inhibitor (SSRI) for the anxiety, but she suffered from side effects and found that she did not get any symptomatic relief.

What treatments can be offered to Anna?

Age: 35 years old

Height: 5'7"

BMI: 22

Current insomnia management: Sleep hygiene measures, including adjusting bedroom light and noise levels, and avoiding caffeine and alcohol at night.

Insomnia as an independent, psychobiological disorder

A paradigm shift in the definition of insomnia

There has been a major advancement in the acknowledgement of insomnia as an **independent disorder** that warrants specific attention in clinical practice. Published in 2013, the Diagnostic and Statistical Manual of the American Psychiatric Association (DSM-5) eliminated artificial distinctions between primary and secondary insomnia, instead establishing insomnia disorder as an **overarching diagnostic category**.³

The most recent version of the International Classification of Diseases (ICD-11, 2019) also follows the approach taken in the DSM-5, removing the distinction between “organic” and “non-organic” insomnia.¹⁶ There is now a dedicated chapter for **sleep-wake disorders** in which insomnia is categorised as either long-term or short-term.¹⁷

Insomnia frequently occurs as a co-morbid condition alongside other disorders; the ICD-11 and DSM-5 both allow for insomnia to be considered as a **co-morbidity** rather than a symptom of another disorder,¹⁶ **encouraging clinicians to assess and treat sleep disturbances alongside other conditions.**

Insomnia and an overactive wake drive

An overactive wake drive can be defined as: “a state of relatively increased **24-hr** cognitive, emotional, physiological and cortical arousal.”¹⁸

Perpetuating factors can lead to the development of long-term insomnia. The **overactive wake drive** (or hyperarousal) model suggests that **conditioned arousal** acts as a perpetuating factor.¹⁹

In response to a precipitating factor (a stressor), **cognitive-behavioural** and **neurobiological** changes occur. Rather than being associated with sleep, the bed and the sleep environment become **stimuli causing anxiety and hyperarousal**. Further neurobiological and cognitive-behavioural changes such as excessive focus on sleep patterns and withdrawal from normal activities act as perpetuating factors that lead to the development of long-term insomnia.¹⁹ This overactive wake drive leads to patients feeling “**tired but wired**” and unable to sleep despite being exhausted (Fig. 5).²⁰

This model therefore assumes that long-term insomnia is caused by an interplay between **physiological** and **psychological** factors and can therefore be conceptualised as a **psychobiological** disorder.¹⁹

The physiological component of the overactive wake drive model can be demonstrated using specialised tests. Neuroimaging studies suggest that individuals with insomnia experience higher brain metabolism both during

sleep and while awake.²¹ Additionally, polysomnography (PSG) results show that people with insomnia display characteristics of an overactive wake drive.²² While these tests are not needed to diagnose and treat insomnia, they indicate a “**drive to wakefulness**” in people with insomnia.

What are the implications of insomnia as a psychobiological disorder?

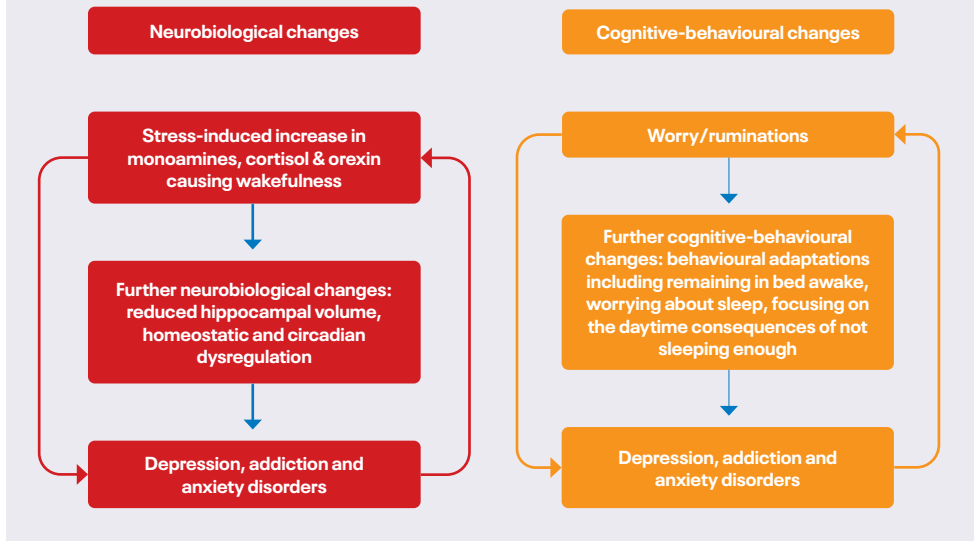
Insomnia is a **psychobiological** disorder, associated with **structural** and **functional** changes to the brain as well as

changes on a **psychological** level.¹⁹

The effective management of chronic insomnia, similar to other chronic illnesses, could necessitate long-term treatment to ensure a sustained effect.²³

Clinicians treating insomnia should therefore approach it as they would other long-term conditions. Symptoms may worsen when therapy is discontinued, and this can lead to further anticipatory anxiety around sleep.²³

Figure 5: Overactive wake drive in insomnia characterised by neurocognitive changes.



Current treatments for insomnia and guidance on use

Treatment options for insomnia include non-pharmacological approaches (cognitive behavioural therapy for insomnia [CBTi]) and pharmacological treatment options.¹⁶

CBTi is recommended as the **first-line treatment option** by the National Institute for Health and Care Excellence (NICE)²⁴ and Scottish Medicines

Consortium (SMC)²⁵ for all patients with long-term insomnia. European guidance on CBTi includes those that have other co-morbidities or mental health problems.¹⁶ Where CBTi is not effective, not available, or declined by the patient, a pharmacological option can be considered.¹⁷



KOBUSLOW / VAGGETTY IMAGES

Anna's GP recommends she starts CBTi

Anna's GP has recommended she try CBTi as a first-line treatment option. He has also provided her with advice on sleep hygiene practices and has recommended she book a follow up appointment to discuss how she has responded to the CBTi.

Cognitive behavioural therapy for insomnia

CBTi can be delivered by a clinician or a therapist either face to face or digitally. Treatment is administered over 4–8 sessions and has a number of components.¹⁶

CBTi component	What it involves
Psychoeducation/ sleep hygiene ¹⁶	Foundational information on sleep, e.g., sleep-wake pattern regulation, impact of aging. This information is integrated into the other components of CBTi to explain their importance and how they work Sleep hygiene measures are also reinforced, e.g., routine, avoiding caffeine/alcohol (on its own, sleep hygiene does not constitute evidence-based treatment for insomnia)
Relaxation therapy	The most frequently used techniques include: Abbreviated progressive muscle relaxation (APMR) : a technique where various muscle groups are tensed and relaxed systematically from head to feet. The patient focuses on the contrasting sensation of tensing and relaxing ²⁶ Autogenic training : A set of simple meditative exercises that focus the mind on the body's experiences of, e.g., a calm heart beat and slower breathing ²⁷ Visualisation (imagery) exercises : Using mental images to help relax the mind and body and create a sense of wellbeing ²⁸
Sleep restriction therapy	The amount of time spent in bed is initially restricted, and then gradually increased. The most powerful component of CBTi, but poorly named as it is time in bed, not sleep, that is restricted. This includes keeping a sleep journal ²⁹
Stimulus control therapy	A set of instructions that aim to reestablish a connection where "bed" equals "sleep" ¹⁶ - for example, patients follow instructions to get out of bed when it's difficult to fall asleep or when they are awake for more than 10 minutes, only going back to bed when tired again. ¹⁶
Cognitive therapeutics	Several interventions, including: ¹⁶ Cognitive control : "putting the day to rest" before going to sleep Paradoxical intention : not making an effort to sleep and instead trying to stay awake

While CBTi is recommended as first-line treatment for patients with long-term insomnia, a huge problem across Europe and the UK is that face-to-face CBTi is **not**

available for everyone. While digital CBTi is an alternative option, fully automated digital CBTi is associated with high dropout rates.¹⁶

How has Anna been getting along with CBTi?

Anna has tried the sleep hygiene advice and digital CBTi as recommended by her GP but is still struggling to stay asleep and wakes up multiple times at night.

The lack of proper sleep is having an impact at work and at home, and she is finding she is not able to remain as active during the day as she used to be.

Anna has returned to her GP who has suggested trying daridorexant at the standard dose of 50mg once at night.

Pharmacological treatment options

Benzodiazepines (BZs) and Z-drugs

BZs (e.g., diazepam, lorazepam) and Z-drugs (e.g., eszopiclone, zopiclone and zolpidem)³⁰ are allosteric agonists of the gamma-aminobutyric acid (GABA) receptor, enhancing the effects of the major central nervous system inhibitory neurotransmitter, GABA.³¹ Both groups have hypnotic properties³² and are effective in treating insomnia.

BZs and Z-drugs are recommended for short-term insomnia management,³³ with treatment generally not recommended to exceed 4 weeks including any tapering off.³¹ However, in certain cases, depending on the medication, the treatment period may be extended to a maximum duration of 6 months.³⁴ Although hypnotic medications can provide relief from the symptoms of insomnia, they do not treat any underlying cause.³¹

BZs have relatively long half-lives compared with Z-drugs. The shorter half-life of zolpidem may make it more appropriate for patients whose difficulty is in falling asleep compared with those whose issues relate to staying asleep, which should be considered on a case-by-case basis.³⁵



WAND_PROGRAM/VIA GETTY IMAGES

The patient case is fictional and presented for illustrative purposes only. The effects of daridorexant may vary from patient to patient.



MICROGEN / MAGGETT IMAGES

Challenges associated with the long-term use of these treatments for chronic insomnia include:³⁶

- The risk of developing tolerance and dependence, and subsequent withdrawal, may increase over time³¹
- The British Association for Psychopharmacology consensus statement notes that dependence is “*not inevitable with hypnotic therapy up to 1 year*” with eszopiclone or zolpidem³⁵
- Consideration of whether hypnotic treatment should be used in the long-term is a controversial area³⁵
- Residual effects are commonly seen with long-acting BZs³⁰
- Withdrawal effects are commonly seen with short-acting BZs
 - Withdrawal symptoms may develop within a day of stopping a short-acting BZ but may develop up to 3 weeks after cessation of a long-acting BZ³¹
- Sedative effects of Z-drugs may persist into the following day³¹

While treatment is recommended for short term use only, BZs are often

widely used across European countries for a longer duration; a pilot survey investigating the pharmacological treatment of long-term insomnia in 5 European countries found that BZs were used for an average of 7.1 weeks in the UK to treat long-term insomnia.³⁶

The use of these medications for long-term treatment of chronic insomnia is often due to **limited resources available** to GPs, and this includes, until recently, a lack of approved pharmacotherapy for long-term insomnia.³⁶

Off-label prescribing of low-dose sedating antidepressants and use of antipsychotics

Sedating antidepressants do not have a general indication for treatment of insomnia, but are sometimes used off-label, usually prescribed at lower doses for insomnia than those used for depression.¹⁶ A meta-analysis assessing the safety, tolerability and effectiveness of antidepressants for insomnia found little evidence for their use.³⁷ The British Association for Psychopharmacology

consensus statement highlights that older antidepressant medications may affect a wider range of brain receptors and have carry-over effects, with little known about how their effect compares with medications that are approved for insomnia.³⁵ As such, they should be used cautiously on a case-by-case basis, where benefit to the patient outweighs risks.

Although some antipsychotic medications may explicitly mention insomnia as an indication, there are no randomised-controlled trials supporting their use for short- or long-term insomnia (with or without comorbid disorders).¹⁶

Melatonin (modified-release)

Melatonin, a hormone secreted by the pineal gland that is structurally related to serotonin, is involved in the circadian rhythm, peaking during the hours of darkness. Its mechanism of action is believed to be via the MT-receptors, which are involved in circadian rhythm and sleep regulation. The sedative effect of melatonin increases the propensity for sleep and can advance or delay circadian rhythmicity, depending on administration time relative to the natural secretion peak.³⁸

Modified-release melatonin is used for the short-term treatment of insomnia (for up to 13 weeks) in adult patients of ≥ 55 years of age,³⁹ with beneficial effects on daytime functioning having been seen in this group.³⁵ The shorter half-life of melatonin may make it more appropriate

for issues relating to sleep onset rather than regular awakening, which should be considered on a case-by-case basis.

Antihistamines

Use of antihistamine medications (e.g., diphenhydramine or promethazine) in the treatment of insomnia is not currently supported by sufficient clinical evidence to be recommended in the European Insomnia Guidelines.¹⁶

Dual orexin receptor antagonists (DORAs)

DORAs have likely marked the most **notable recent development** in the pharmacological treatment of insomnia.¹⁶ Orexin, a neuropeptide, was discovered in 1998 and it was soon found to have a role in promoting wakefulness.⁴⁰ In the USA, the first DORA gained approval for the treatment of insomnia in 2014,⁴¹ with the second DORA approved in 2019. In 2023, daridorexant (QUVIVIQ™) was approved in the UK²⁴ for the treatment of long-term insomnia, a year after approval in Europe.⁴²



What is daridorexant?

How does it work?

Daridorexant works by blocking orexin type 1 (OX1R) and type 2 (OX2R) receptors thereby preventing the wake-promoting orexin A and orexin B neuropeptides from binding.⁴¹ These receptors and neuropeptides make up the orexin system. The orexin system stimulates specific neurons, leading to the release of neurotransmitters (dopamine, serotonin, histamine, acetylcholine, norepinephrine) that promote wakefulness (Fig. 6).⁴³

Normally, orexin levels increase during the day and then fall at night; however, as illustrated by the overactive wake drive model (see Fig. 5), the wake-promoting regions of the brain remain active at night in patients with long-term insomnia.⁴³ DORAs work differently from other

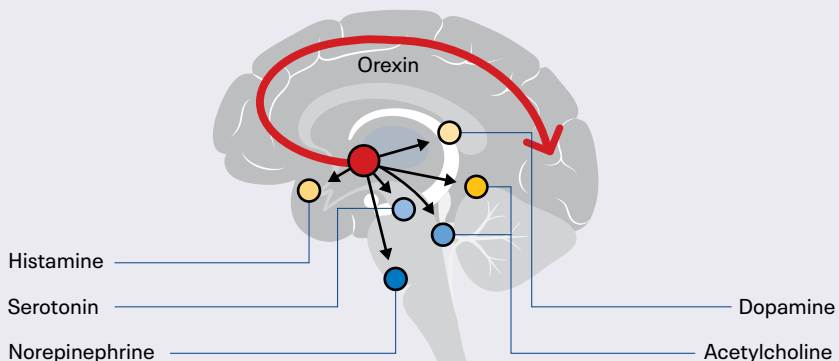
hypnotics and selectively block the activity of orexin rather than sedating the central nervous system. In doing so, the activity of the wake-promoting neurotransmitters (Figure 5) is reduced.⁴³

NICE Guidance 2023 and SMC Advice 2024: Daridorexant (QUVIVIQ™) for treating long-term insomnia

NICE recommends and the SMC has accepted QUVIVIQ™ (daridorexant) for treating insomnia in adults with symptoms lasting for 3 nights or more per week (NICE TA922) for at least 3 months, and whose daytime functioning is considerably affected, only if:^{24,44}

- Cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or
- CBTi is unsuitable or not available

Figure 6: Release of wake promoting neurotransmitters via activation of the orexin system⁴³



Access to CBTi varies across the country, and while digital sleep improvement programmes are also recommended, some may struggle with online CBTi.²⁴

Therefore, guidance from NICE and SMC is an important step for ensuring **timely treatment** for patients with long-term insomnia who do not have access to CBTi.

Guidance also recommends that duration of treatment with daridorexant should be as short as possible and treatment should be reassessed within 3 months of starting daridorexant; where

treatment is continued, effectiveness should be assessed at regular intervals. If long-term insomnia does not respond adequately, treatment should be stopped.

The recommendations included in the NICE technology appraisal provide GPs with a targeted treatment option for long-term insomnia that does not require referral to sleep specialists. The appraisal **empowers GPs to take action on long-term insomnia** with a treatment option that works differently to currently available insomnia medications.



How is daridorexant different from other hypnotics?

A targeted treatment option for long-term insomnia

The lack of available treatment options for patients with long-term insomnia can lead to people feeling frustrated and at crisis point.⁴⁵ Other pharmacological treatments create a **paradoxical situation**: these medications are not recommended for long-term use and yet they are being used to manage a long-term condition.³⁶ The efficacy of BZs and Z-drugs (i.e., GABA receptor agonists) is known to decrease with time and dependence.⁴⁶ In addition, such medications act through induction of global depression of the brain rather than through targeting the induction and maintenance of sleep.⁴⁶

The availability of daridorexant could provide a treatment option to patients who are persistently deprived of restorative sleep⁴⁵ (sleep that allows the body and brain to recuperate)⁴⁷ and provides a targeted treatment option for long-term insomnia.

Daridorexant specifically targets the wake-promoting orexin system,⁴⁸ unlike BZs and Z-drugs, which induce global sedation.⁴⁶ This targeted approach maintains the amount of time spent in each of the various stages of sleep, sustaining the cyclical process.⁴⁸

Improvements in sleep complemented by improvements in daytime functioning

Insomnia is a 24-hour condition and therefore treatment options should aim to improve both nighttime and daytime

symptoms.⁴⁶ BZs and Z-drugs cause a global depression of the brain⁴⁶ and therefore may lead to residual effects the following day.³⁰

Rather than inducing global sedation, daridorexant works by inhibiting orexin receptors, and thereby preventing the activation of the wake-promoting orexin system, and in doing so, preserving the “normal sleep architecture,” ensuring that the proportion of time spent in the different stages of sleep is preserved.⁴⁸

The impact on **daytime functioning** of daridorexant was investigated by two placebo-controlled phase 3 trials, which used the Insomnia Daytime Symptoms and Impacts Questionnaire (IDSIQ; a validated patient-reported outcome tool⁴⁹) to measure daytime functioning.⁴⁶

Participants receiving 50mg daridorexant reported an improvement in **all aspects of daytime functioning**, as assessed by the IDSIQ. This may be explained by:⁴⁶

- Night after night improvements in **induction** and **maintenance** of sleep, without affecting the **proportion** of time spent in each sleep stage
- Absence of next-morning residual sleepiness due to the optimal 8-hour half-life of daridorexant. This ensures that next-morning residual effects are minimised⁵⁰

The absence of next-morning residual sleepiness is particularly important for older people due to the risk of falls;⁵¹ a study assessing the efficacy and safety



Latency to Persistent Sleep (LPS): time between lights out and the first 10 min of sleep⁵⁴



Wakefulness after sleep onset (WASO): time spent awake after initially falling asleep⁵³

of daridorexant in younger (<65 years) and older adults (≥65 years) found similar improvements in:⁵²

- Morning sleepiness
- Daytime ability to function
- Alertness during the day
- Minimal residual next-day effects

Improvements in the induction and maintenance of sleep

The nighttime efficacy of daridorexant has been assessed by measuring the impact on LPS⁵⁴ and WASO, as primary endpoints. A phase 2 study comparing daridorexant (at varying doses) with placebo and zolpidem found that daridorexant demonstrated:⁵⁰

● **A significant dose-response relationship** in reducing **WASO** from baseline to days 1 and 2. This was

maintained at days 15 and 16, and days 28 and 29

● **A significant dose-relationship** in reducing LPS from baseline to days 1 and 2, with effects **maintained** at days 15 and 16, and days 28 and 29

By indirect and exploratory comparison to daridorexant, zolpidem improved improved LPS but had no significant effect on WASO; these results were analysed separately.⁵⁰

These findings were supported by two multicentre, randomised, double-blind, placebo-controlled phase 3 trials:⁴⁶

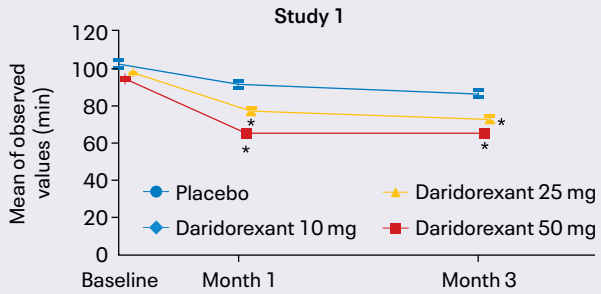
- Study 1 (N=930) – 75 hospitals and sleep centres in 10 countries comparing daridorexant 50mg, 25mg and placebo
- Study 2 (N=924) – 81 hospitals and sleep centres (different from study 1) in 11 countries comparing daridorexant 50mg, 25mg and placebo; please note that daridorexant 10mg is not a licensed dose.

In study 1 at the doses of 25 and 50mg, using objective PSG recordings, daridorexant significantly reduced WASO and LPS compared with placebo (Fig. 7 + 8).⁴⁶

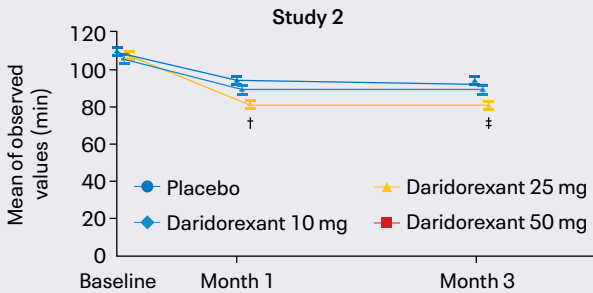
The change from baseline in **self-reported total sleep time (sTST) was significant at both months 1** (p<0.0001 daridorexant 50mg; p=0.0013 daridorexant 25mg) **and 3** (p<0.0001 daridorexant 50mg; p=0.033 daridorexant 25mg) in study 1 and across both doses and timepoints in study 2.⁴⁶

(10mg daridorexant was not found to be efficacious⁴⁶ and is not licensed for use).

Figure 7: Mean observed WASO values in study 1 and study 2⁴⁶



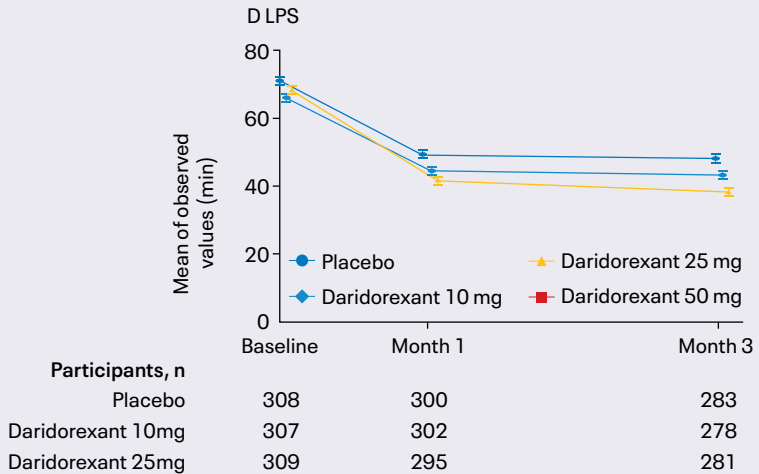
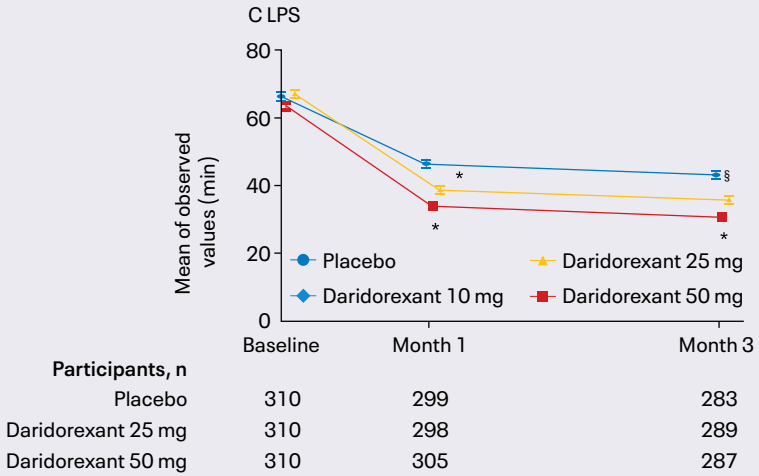
Participants, n			
Placebo	310	299	283
Daridorexant 25 mg	310	298	289
Daridorexant 50 mg	310	305	287



Participants, n			
Placebo	308	300	283
Daridorexant 10 mg	307	302	278
Daridorexant 25 mg	309	295	281

*p<0.0001. †p=0.0001. ‡p=0.0028. §p=0.0015

Figure 8: Mean observed latency to persistent sleep values in study 1 and study 2⁴⁶



[†]p<0.0001. [‡]p=0.0001. ^{*}p=0.0028. [§]p=0.0015

Daridorexant shows no evidence of rebound insomnia or withdrawal symptoms

Rebound insomnia can be defined as: “worsening of insomnia symptoms compared to baseline upon medication discontinuation.”²³

BNF treatment summaries highlight that the major drawback of the long-term use of BZs/Z-drugs is that “withdrawal can cause **rebound insomnia** and a withdrawal syndrome.”³⁰

The risk of dependence with BZs and Z-drugs means that treatment strategies are often needed when discontinuing these medications.⁵⁵

In contrast, in the phase 3 trials with daridorexant there was no evidence of withdrawal-related symptoms or rebound insomnia upon treatment discontinuation after 3-months or 12-months, even upon abrupt discontinuation.^{46, 56}



Taking daridorexant - how quickly can patients benefit and what is the safety profile?

In phase 2 studies, patient responses to daridorexant varied; however, improvements in nighttime efficacy measures (LPS and WASO) were seen in some patients from days 1 and 2, and were maintained across the study.⁵⁰

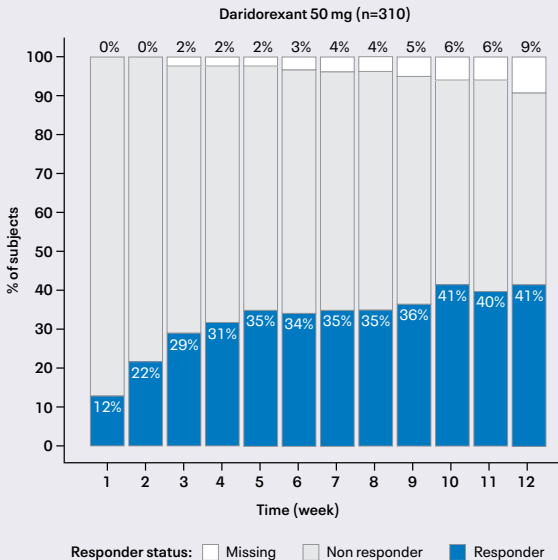
In the phase 3 studies, although the drug response varied between patients,

nighttime and daytime efficacy measures continuously improved over the first 3 months⁴⁶ of treatment with daridorexant (Fig. 9), starting in week one and were maintained with up to 12 months of nightly use.⁵⁶

Results indicate that while some patients may report early improvement in

Figure 9: Proportion of patients perceiving a response while receiving daridorexant 50mg.⁵⁷

A reduction in IDSIQ total score indicates improvement in daytime functioning; participants were classed as "responders" if the decrease from baseline in IDSIQ total score at a certain timepoint was ≥ 20 points.⁵⁷



What's next for Anna?

daytime functioning, this **improvement may be more progressive** in others.⁵⁷ Long-term follow-up data of the phase 3 trials⁵⁶ showed that improvements in **sleep quantity** and **daytime functioning** were maintained with up to 12 months of continuous treatment.

As with many treatments for chronic conditions, where consistent use is required for sustained effect, **improvements with daridorexant gradually increase over time.**

Safety

In clinical trials and post-marketing experience, the most frequently reported adverse reactions were headache and somnolence. The majority of adverse reactions were mild to moderate in intensity and the adverse reaction profile in elderly subjects was consistent with younger adult subjects.⁵⁸

The safety profile of daridorexant when taken nightly has been demonstrated with up to 12 months of continuous treatment.⁵⁶

Patients who completed the initial 12-week trials were invited to enrol in a double-blind 40-week extension study to assess the long-term safety and tolerability of daridorexant. This follow-up study found no new safety signals and no signs that improvements were waning towards the end of the 1-year study.⁵⁶ There were **“no signs of tolerance, physical dependence or rebound insomnia”** with daridorexant.⁵⁶

Anna has been on daridorexant for a month and has found her symptoms have improved. She no longer wakes up multiple times at night and has found that she is no longer feeling tired during the day. Her GP has advised her to continue taking daridorexant and will assess her at regular intervals.



KOBSLOUW/VIA GETTY IMAGES

The patient case is fictional and presented for illustrative purposes only. The effects of daridorexant may vary from patient to patient.

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Insomnia is a 24-hour condition; in addition to nighttime symptoms, insomnia impacts daily functioning, which can be debilitating.¹ Insomnia has been linked to a number of chronic health conditions² and the impact extends far beyond the individual, with ripple effects that can affect families, employers, and even global economies.³

Pharmacological treatments such as benzodiazepines and Z-drugs are usually indicated for treating insomnia up to a maximum of 4 weeks,^{4,5} although some may be prescribed for up to 6 months.⁶ Paradoxically, these medications are not recommended for long-term use and yet they are being used to manage a long-term condition.⁷



Dual orexin receptor antagonists (DORAs) have been available since 2014 and work differently to other pharmacological treatment options. QUVIVIQ (daridorexant) is a DORA indicated for patients with long-term insomnia.⁸ QUVIVIQ targets the orexin system, reducing the activity of wake-promoting neurotransmitters.⁹

Daridorexant is recommended by NICE¹⁰ and accepted by the SMC¹¹ for treating insomnia in adults with symptoms lasting for 3 nights or more per week for at least 3 months, and whose daytime functioning is considerably affected, only if:^{10,11}

- Cognitive behavioural therapy for insomnia (CBTi) has been tried but not worked, or
- CBTi is unsuitable or not available



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Prescribing information



For full prescribing and adverse event reporting information, please scan the QR code or visit <https://prescribing-information-quviviq.idorsia.uk/>

UK-DA-00849 | August 2025.

Adverse events must be reported. Healthcare professionals are asked to report any suspected adverse reactions via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in Google play or Apple App store. Adverse events should also be reported to ds.safety.uk@idorsia.com