

Using melatonin to treat sleep disorders in children and young people with ADHD

Information for the public

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About this information

This information explains the evidence summary about the unlicensed and off-label use of melatonin to improve sleep for children and young people (under the age of 18 years) with attention deficit hyperactivity disorder (ADHD). The evidence summary is an overview of the available information about this medicine. It aims to help prescribers and patients, and their parents or carers if appropriate, when they are considering whether or not to use an unlicensed or off-label treatment. The summary does not contain recommendations from NICE on whether the medicine should be used.

Licensing medicines

In the UK, medicines need to have a licence before they can be marketed. To get a licence, the manufacturer of the medicine has to provide evidence that shows that the medicine works well enough and is safe enough to be used for a specific condition and for a specific group of patients, and that they can manufacture the medicine to the required quality. Medicines can be prescribed without a licence (an 'unlicensed medicine') if there is no suitable licensed alternative and it is likely to benefit the patient.

A medicine can also be prescribed 'off-label'. This means the prescriber wants to use it in a different way than is set out in the terms of its licence. This could mean using the medicine for a different condition or a different group of patients, or it could mean a change in the dose or that the medicine is taken in a different way. There is more information about licensing medicines on [NHS Choices](#).

What are sleep disorders in children with ADHD?

Sleep disorders include problems getting to sleep or staying asleep. The impact of this lack of sleep can vary greatly in its severity. Lack of sleep can affect the mood of the child or young person as well as affecting their concentration and behaviour.

Sleep disorders are more common in children with ADHD. ADHD is one of the most common behavioural disorders in children and young people. Symptoms of ADHD can include being:

- inattentive – unable to concentrate for very long or finish a task, disorganised, often losing things, easily distracted and forgetful, unable to listen when people are talking
- hyperactive – fidgety and unable to sit still, restless (children may be running or climbing much of the time), talking constantly, noisy, having difficulty doing quiet activities
- impulsive – speaking without thinking about the consequences, interrupting other people, unable to wait or take their turn.

About melatonin

Melatonin is a naturally occurring hormone produced by the brain. It is involved in regulating a person's body clock and helping to regulate sleep patterns.

Just 1 melatonin product, called Circadin, is licensed for use in the UK. It can only be obtained with a prescription and comes in the form of a 'prolonged-release' tablet. Prolonged-release means that the drug treatment continues working over a number of hours as the active ingredient is released slowly in the body. This tablet is licensed for treating sleep disorders over a short period of time in adults who are aged 55 or over. It is not licensed for use in any other age group, and so using prolonged-release melatonin in children and young people under 18 is described as 'off-label'.

Other melatonin products, some in the form of 'immediate-release' capsules, tablets or liquids, are available from specialist suppliers and on the internet. These are not licensed for use in any patient group in the UK and so are known as 'unlicensed'.

The main treatments available for children and young people with sleep disorders are non-drug treatments, including good 'sleep hygiene'. Good sleep hygiene includes day-to-day things that can be done at home to help children and young people sleep. This includes advice such as having fixed times for going to bed, avoiding exercise and eating a heavy meal near bedtime, keeping the bedroom comfortable and relaxing near bedtime.

Summary of possible benefits and harms

Three small studies have looked at how well melatonin works for treating sleep disorders in children aged 6 to 14 years with ADHD. Taken together, only 124 children and young people were involved, including only 19 children and young people in the smallest study. Importantly, children in these studies were given unlicensed melatonin. None of these studies used off-label prolonged-release melatonin and none of them took place in the UK. Other studies have looked at melatonin in other groups, such as children with neurodevelopmental disorders, but these are less relevant to children with ADHD.

All children who took part in the studies had been diagnosed with ADHD and also problems falling asleep. In 2 of these studies, children took either unlicensed melatonin or placebo (a dummy treatment) every night before bedtime for a period of between 10 days and 4 weeks to see if it could help them fall asleep. A third study monitored the children who had taken part in the largest of the studies (mentioned above) for around 3 and a half years to see whether it is safe to take melatonin for this longer period. Most children did not take melatonin for the whole 3 and a half years; on average, children took melatonin for 18 months.

How well does melatonin work?

This small amount of evidence indicated that taking unlicensed melatonin just before bedtime reduced the time it took the children to fall asleep (after lights out or when they were put to bed) by approximately 20 minutes. It also improved the total time they were asleep by an average of approximately 15 to 20 minutes.

The effect of melatonin in the medium to long term is uncertain because the studies have not accurately assessed how well melatonin works by comparing it with placebo (a dummy treatment) beyond 4 weeks. The longer study (mentioned above) did not include any children and young people taking placebo.

It is important to note that there was no good quality evidence showing that melatonin improves the behaviour or mental function of children or young people with ADHD, or their quality of life. However, parental satisfaction with melatonin was high, with 87.8% of parents expressing the opinion that "melatonin is an effective therapy for the sleep onset problems of my child", 70.8% that "melatonin improved daytime behaviour of my child" and 60.9% that "melatonin improved the mood of my child". These were the views of a group of 94 parents whose children continued taking melatonin for different time periods after they had taken part in 1 of the studies that looked at how

well it worked. They may not represent the views of all parents of children who have tried using melatonin.

One of the studies indicated that the improvements in sleep experienced through taking melatonin may be lost if the medication is stopped.

However, the melatonin products used in these studies are unlicensed in the UK which means that they are not subject to the same high-quality effectiveness and safety standards as licensed medicines. Therefore, how well different unlicensed melatonin products work and how safe they are may vary depending on which 1 is used. Also these small studies were done in the Netherlands and Canada and so their findings may not apply to UK children and young people with ADHD.

What are the possible harms or side effects?

The number of side effects, and how severe they were, was found to be similar between children given placebo (a dummy treatment) and those given melatonin in the studies. However, the studies were small, which may mean that they could have missed differences in side effects between the groups. The most common side effects reported in those given melatonin in the larger of the studies were headache, hyperactivity, dizziness and abdominal pain (each of these side effects were reported for about 2 or 3 children out of 105; note 1 child could have more than one side effect). There were no reports of melatonin causing serious side effects in the studies.

Based on these small studies, unlicensed melatonin appeared relatively safe in the short term (using it for up to 4 weeks) and medium term (using it for up to 18 months). However, all the studies were small so infrequent side effects may not have been detected; the safety of long term melatonin use in children and young people with ADHD is unclear.

Please note that the results of the research studies only indicate the benefits and harms for the population in the studies. It is not possible to predict what the benefits and harms will be for an individual patient being treated with melatonin.

Prescribing melatonin

If a prescriber decides to prescribe an unlicensed or off-label medicine, they must follow their professional guidance. For doctors this is the General Medical Council's [good practice guidelines](#). This guidance includes giving information about the treatment and discussing the possible benefits and harms so that the patient, and their parent or carer if appropriate, has enough information to decide whether or not to have the treatment. This is called giving informed consent.

The full version of the summary aimed at healthcare professionals is available at <https://publications.nice.org.uk/esuom2-sleep-disorders-in-children-and-young-people-with-attention-deficit-hyperactivity-disorder-esuom2/>. The summary for healthcare professionals does not contain recommendations from NICE on whether the medicine should be used.

If your doctor is suggesting that your child might try melatonin to help their sleep disorder, and they also have ADHD, you might like to ask some of the questions below.

Questions to ask

- Why is my child being offered an unlicensed or off-label medicine?
- What does the treatment involve?
- What are the benefits they might get?
- How good are their chances of getting those benefits?
- Could having the treatment make them feel worse?
- Are there alternative treatments?
- What are the risks of the treatment?
- Are the risks minor or serious? How likely are they to happen?
- What may happen if they don't have the treatment?

More information

The evidence summary and this information for the public were produced for NICE by Bazian Ltd.

NICE has published [information](#) about how evidence summaries for unlicensed and off-label medicines are developed.

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