

CONCERTA® (methylphenidate HCl ER) Management of Sleep Disturbance

SUMMARY

- **Coskun et al (2008)**¹ presented the case of a 10-year-old male diagnosed with attention-deficit/hyperactivity disorder (ADHD), oppositional defiant disorder, and generalized and separation anxiety disorders. The patient was started on mirtazapine, which resulted in improved sleep and appetite, with no recurrence of tactile or visual hallucinations.
- **Herguner et al (2011)**² conducted a retrospective chart review evaluating mirtazapine for managing weight loss and insomnia in 18 pediatric ADHD patients treated with CONCERTA. All patients gained weight (mean, 2.1 kg), and 14 of 16 patients who had insomnia while taking CONCERTA alone reported improvements in sleep disturbances following mirtazapine administration.
- **Cortese et al (2013)**³ conducted a clinical review, which discusses general behavioral approaches to managing insomnia in youths with ADHD, and is summarized in the [CLINICAL DATA](#) section below.

PRODUCT LABELING

Please refer to the following section of the enclosed Full Prescribing Information that is relevant to your inquiry: ADVERSE REACTIONS.⁴

CLINICAL DATA

Case Report

Coskun et al (2008)¹ described the case of a 10-year-old male patient diagnosed with ADHD, oppositional defiant disorder, and generalized and separation anxiety disorders.

- The patient was initially treated with CONCERTA (18 mg/day) and fluoxetine (10 mg/day) and experienced an acute-onset episode of intense hallucinations on the fourth day of treatment.
- Both medications were discontinued, and the patient was reassessed after a 10-day drug-free interval, during which no recurrence of symptoms was observed.
- Due to persistent behavioral problems, the patient was reinitiated with CONCERTA monotherapy (18 mg/day) under close observation.
- Over the following 2 weeks, his behavior problems showed moderate improvement, with no recurrence of hallucinations; however, sleep disturbances worsened and appetite decreased.
- Subsequently, the patient was initiated with mirtazapine (15 mg/day at bedtime), which resulted in improved sleep and appetite, with no recurrence of tactile or visual hallucinations reported during 2 months.

Review

Herguner et al (2011)² conducted a retrospective chart review to assess the efficacy of mirtazapine in managing weight loss and insomnia caused by CONCERTA in children and adolescents diagnosed with ADHD.

- The study identified 18 eligible patients with ADHD who were prescribed mirtazapine for weight loss and/or insomnia during CONCERTA treatment.
- Two patients discontinued mirtazapine due to excessive daytime sedation within the first week. Sixteen patients were well tolerated with the administration of mirtazapine, and no additional side effects were observed during treatment.
- All patients experienced weight gain (mean, 2.1 kg) during concomitant mirtazapine treatment. Additionally, 14 of 16 patients who had insomnia while taking CONCERTA alone reported improvements in sleep disturbances following mirtazapine administration.

Cortese et al (2013)³ conducted a clinical review that discussed general behavioral approaches to managing insomnia in youths with ADHD. This publication is available upon request. Healthy sleep practices, commonly referred to as “sleep hygiene,” include modifiable daytime, bedtime, and nighttime practices that have a positive impact on sleep (see Table 1: [Healthy Sleep Practices](#)). Table 2 below provides additional specific tips for healthy sleep habits in ADHD. Behavioral interventions, adapted for ADHD children, should be the first-line treatment. See Table 2: [Tips for Healthy Sleep Practice in ADHD](#).

Healthy Sleep Practices³

Recommended	Not Recommended
Goes to bed at about the same time	Drinks lots of liquids before bedtime
Goes to bed in the same place	Does things that are alerting
Sleeps alone	Uses the bed for things other than sleep
Consumes caffeine and naps a maximum of 4 hours before bedtime	Put to bed after falling asleep
Has a calming bedtime routine	Stays up past usual bedtime
Gets out of bed at the same time in the morning	
Note: Selected items are adapted from the Children’s Hygiene Scale.	

Tips for Healthy Sleep Practice in ADHD³

Practices
Promoting Sleep Regulation • Maintain an organized and consistent sleep-wake cycle • Set and enforce a consistent bedtime on weekdays and weekends • Keep a regular daily schedule of activities, including meals • Avoid bright light in the bedroom at bedtime and during the night • Increase light exposure in the morning • Establish an appropriate napping schedule
Promoting Sleep Conditioning • Establish a regular and consistent bedtime routine • Limit activities that promote wakefulness while in bed (watching TV, using the cell phone); use the bed for sleep only • Do not use the bed for punishment (“time out”) • Avoid using staying up late as a reward for good behavior and going to bed as a punishment for undesired behavior • Avoid sleeping in environments other than the bedrooms (for example, couch, car)
Reducing Arousal and Promoting Relaxation • Keep electronics out of the bedroom and limit the use of electronics before bedtime • Reduce stimulating play at bedtime • Avoid heavy meals and vigorous exercise close to bedtime • Reduce cognitive and emotional stimulation before bedtime • Eliminate caffeine • Include activities in the bedtime routine that are relaxing and calming
Promoting Adequate Sleep Quantity and Quality • Set an age-appropriate bedtime and wake time to ensure adequate sleep • Maintain a safe and comfortable sleeping environment (low noise and light levels, cooler temperatures, age-appropriate bedding and sleeping surface)
Abbreviation: ADHD, attention-deficit/hyperactivity disorder.

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 23 September 2025.

REFERENCES

1. Coskun M, Zoroglu S. Tactile and visual hallucinations in a child with methylphenidate and fluoxetine combination. *J Clin Psychopharmacol*. 2008;28(6):723-725.
2. Herguner S, Herguner A. Mirtazapine treatment for weight loss and insomnia associated with methylphenidate: a chart review. Abstract presented at: 4th International Congress on Psychopharmacology; November 23-27, 2011; Antalya, Turkey.
3. Cortese S, Brown TE, Corkum P, et al. Assessment and management of sleep problems in youths with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2013;52(8):784-796.
4. CONCERTA (methylphenidate HCl) [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-edb60a5a-a794-4ed6-b7ab-758d0aa94194.