

## **CONCERTA® (methylphenidate HCl ER)**

### **Dosing – Dosing of CONCERTA Over 54 mg Per Day in Children**

#### **SUMMARY**

- Daily dosages of CONCERTA (methylphenidate HCl extended-release [MPH ER]) above 54 mg per day in children (6-12 years old) have not been studied and are not recommended.<sup>1</sup>
- One case report described a 4-year-old boy given 108 mg/day of CONCERTA.<sup>2</sup>

#### **PRODUCT LABELING**

Please refer to the following section of the enclosed Full Prescribing Information that is relevant to your inquiry<sup>1</sup>: DOSAGE AND ADMINISTRATION, Dose Titration.

#### **CLINICAL DATA**

##### **Case Report – CONCERTA Doses >54 mg/day in Children**

**Lipkin et al (2003)**<sup>2</sup> documented the case of a 4-year-old boy who was titrated to a dose of 54 mg/day (2.9 mg/kg/day) of CONCERTA.

- The Child's Clinical Global Impressions (CGI) Global Improvement scores were 3 or higher with Side Effects scores of 2.
- His heart rate and blood pressure were within normal limits.
- Because of behavior problems, his caregiver increased his dose to 108 mg/day (6.1 mg/kg/day) without medical advice.
  - The child experienced notable behavioral improvement (CGI score of 1).
  - His cardiac measures remained normal: heart rate of 102 beats/minute and blood pressure of 99/54 mm Hg.
  - Due to a 1.2 kg weight loss since the previous visit and report of refusal to eat by the caregiver, the clinician decreased his dose to 72 mg/day (3.7 mg/kg/day).
  - After 2 months at this dose, there was a decrease in efficacy as evidenced by an increase in the CGI score to 2.5 compared to 2 when dose was first switched to 72 mg/day.
  - The physician added 5 mg of immediate-release MPH at 3 PM to the regimen (3.5 mg/kg total daily MPH dose), and the CGI score once again improved to 2.

#### **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 03 February 2025. One relevant citation was identified and is summarized above. Please note that the literature search was specific to CONCERTA only, rather than all methylphenidate products. Furthermore, results were limited to studies or case reports in which high doses of CONCERTA were intentionally used to gain additional efficacy benefit or assess safety parameters.

#### **REFERENCES**

1. CONCERTA (methylphenidate HCl) [Prescribing Information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; [https://imedicalknowledge.veevavault.com/ui/approved\\_viewer?token=7994-edb60a5a-a794-4ed6-b7ab-758d0aa94194](https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-edb60a5a-a794-4ed6-b7ab-758d0aa94194).

2. Lipkin PH, Butz AM, Cozen MA. High-Dose Methylphenidate Treatment of Attention Deficit Hyperactivity Disorder in a Preschooler. *J Child Adolesc Psychopharmacol*. 2003;13(1):103-106.