

CONCERTA® (methylphenidate HCl ER) Use in Schizophrenia

SUMMARY

- **Lindermayer et al 2013** conducted a systematic review of trials examining the impact of stimulant medications on neurological soft signs (NSS) and their potential adverse effects, finding that agents such as CONCERTA showed neither improvement nor worsening in treating NSS.¹
- **Skoretz and Tang 2016** reviewed the potential benefits of CONCERTA in impulse dysregulation in a case series of women with a history of schizophrenia and impulsive violence. The addition of CONCERTA was found to be safe and effective in reducing impulsive violent behavior in this select patient group.²
- **Maeder et al 2022** conducted a non-randomized, open-label study evaluated the impact of CONCERTA on cognitive function and brain connectivity in 25 patients with 22q11.2 deletion syndrome (22q11DS), showing significant reductions in attention-deficit/hyperactivity disorder (ADHD) symptom intensity, particularly inattentive symptoms, and improved attention, inhibition, and processing speed.^{3,4}

PRODUCT LABELING

Please refer to the following section of the enclosed Full Prescribing Information that is relevant to your inquiry: DOSAGE AND ADMINISTRATION, WARNING AND PRECAUTIONS, DRUG INTERACTIONS.⁵

CLINICAL DATA

Lindermayer et al 2013 conducted a systematic review of trials that examined the impact of stimulant medications on NSS and the potential for adverse effects. In this review, several studies were summarized where the relationship of CONCERTA and schizophrenic symptoms was studied. One study with a cross-over design, which examined the role of CONCERTA in treating NSS, specifically found neither an improvement nor worsening. The authors of this systematic review concluded that psychostimulant medications may be used cautiously in selecting patients with schizophrenia.¹

Skoretz and Tang 2016 reviewed the potential benefits of CONCERTA in impulse dysregulation in a case series of women with a history of schizophrenia and impulsive violence. They concluded that CONCERTA may have a role in augmenting effects on clozapine.²

Maeder et al 2022 conducted a non-randomized, open-label study that investigated the effects of CONCERTA on cognitive performance and brain connectivity in patients aged 8-24 years with 22q11DS, a neurogenetic condition associated with a high risk of psychiatric disorders, including schizophrenia spectrum disorders. Twenty-five patients were enrolled and divided into the following 2 groups based on prior CONCERTA use: treatment-naïve patients (n=16) and consumers/chronic users (n=9). CONCERTA treatment significantly reduced overall ADHD symptom intensity, particularly inattentive symptoms, and improved attention, inhibition, and processing speed. However, it showed no significant effects on other executive functions, learning, memory, or daily-life behavioral measures, with only emotional control showing a trend toward improvement.^{3,4}

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. Older publications (1950-2000) on this topic were also identified by a literature search and are referenced below for your review.⁶⁻¹⁵

REFERENCES

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