CONCERTA® (methylphenidate HCl ER)
CONCERTA - Treatment Discontinuation

SUMMARY

- There are currently no recommendations for dose tapering in the event that treatment with CONCERTA is discontinued.
- No downward tapering methods were used when subjects were crossed over to another treatment arm in the pivotal trials of CONCERTA in children, adolescents, and adults.[1-7]
- A search of the published literature failed to identify any articles or case reports regarding dose tapering or the possible adverse effects of abruptly discontinuing CONCERTA.

PRODUCT LABELING

Please refer to the following section of the enclosed Full Prescribing Information that is relevant to your inquiry[1]: DOSAGE AND ADMINISTRATION, Dose Reduction and Discontinuation.

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) was conducted on 05 March 2024.

REFERENCES

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5. Wilens TE, McBurnett K, Bukstein O. Multisite controlled study of OROS methylphenidate in the treatment of adolescents with attention-deficit/hyperactivity disorder. *Arch Pediatr Adolesc Med*. 2006;160:82-90.
6. Medori R, Ramos-Quiroga JA, Casas M. A Randomized, Placebo-Controlled Trial of Three Fixed Dosages of Prolonged-Release OROS Methylphenidate in Adults with Attention-Deficit/Hyperactivity Disorder. *Biol Psychiatry*. 2008;63:981–989.
7. Adler LA, Zimmerman B, Starr HL. Efficacy and safety of OROS methylphenidate in adults with attention-deficit/hyperactivity disorder. *J Clin Psychopharmacol*. 2009;29:239-247.