CONCERTA® (methylphenidate HCl ER)
Dosing - Dosage and Administration of CONCERTA

SUMMARY

- CONCERTA (methylphenidate HCl extended-release [MPH ER]) tablets should be administered orally once daily in the morning with or without food. CONCERTA tablets must be swallowed whole with the aid of liquids and must not be chewed, divided, or crushed.[1]
- For children and adolescents new to CONCERTA, the recommended starting dosage is 18 mg once daily. Dosage may be increased by 18 mg/day at weekly intervals and should not exceed 54 mg/day in children and 72 mg/day in adolescents.[1]
- For adult patients new to CONCERTA, the recommended starting dose is 18 or 36 mg/day. Dosage may be increased by 18 mg/day at weekly intervals and should not exceed 72 mg/day.[1]
- For patients currently using MPH, dosing is based on current dose regimen and clinical judgment.[1]
- Alternate doses outside of available dosage strengths may be achieved by combining multiples of 18, 27, or 36 mg to reach desired total daily doses. The two dosage strengths should be taken together, once daily in the morning to achieve the desired total daily dose.[2]
- A literature search did not identify any citations pertaining to dose equivalency or conversion to CONCERTA from other non-methylphenidate stimulant medications.

PRODUCT LABELING

Please refer to the following sections of the enclosed Full Prescribing Information that are relevant to your inquiry[1]: DOSAGE AND ADMINISTRATION, DOSAGE FORMS AND STRENGTHS.

GENERAL DOSING INFORMATION

CONCERTA tablets should be administered orally once daily in the morning with or without food. CONCERTA tablets must be swallowed whole with the aid of liquids and must not be chewed, divided, or crushed.[1]

PATIENTS NEW TO CONCERTA

The recommended starting dose of CONCERTA for patients who are not currently taking MPH or stimulants other than MPH is 18 mg once daily for children and adolescents and 18 or 36 mg once daily for adults (see Table: CONCERTA Recommended Starting Doses and Dose Ranges).[1]

CONCERTA Recommended Starting Doses and Dose Ranges[1]

Patient Age	Recommended Starting Dose	Dose Range
Children 6-12 years of age	18 mg/day	18 to 54 mg/day
Adolescents 13-17 years of age	18 mg/day	18 to 72 mg/day not to exceed 2 mg/kg/day
Adults 18–65 years of age	18 or 36 mg/day	18 to 72 mg/day

PATIENTS CURRENTLY USING METHYLPHENIDATE

The recommended dose of CONCERTA for patients who are currently taking MPH twice daily or three times daily, at doses of 10 to 60 mg/day is provided in Table: Recommended Dose Conversion from Methylphenidate Regimens to CONCERTA. Dosing recommendations are based on the current dose regimen and clinical judgment. Conversion dosage should not exceed 72 mg daily.[1]

Recommended Dose Conversion from Methylphenidate Regimens to CONCERTA[1]

Previous Methylphenidate Daily Dose	Recommended CONCERTA Starting Dose
5 mg methylphenidate twice daily or three times daily	18 mg every morning
10 mg methylphenidate twice daily or three times daily	36 mg every morning
15 mg methylphenidate twice daily or three times daily	54 mg every morning[a]
20 mg methylphenidate twice daily or three times daily	72 mg every morning[b]

[a]Maximum daily dose for children 6 to 12 years of age.
[b]Maximum daily dose for adolescents and adults ages 13 to 65 years of age.

Other methylphenidate regimens: clinical judgment should be used when selecting the starting dose.[1]

DOSE TITRATION

Doses may be increased in 18 mg increments at weekly intervals for patients who have not achieved an optimal response at a lower dose. Daily dosages above 54 mg in children and 72 mg in adolescents have not been studied and are not recommended. Daily dosages above 72 mg in adults are not recommended.[1]

A 27 mg dosage strength is available for physicians who wish to prescribe between the 18 mg and 36 mg dosages.[1]

MAINTENANCE/EXTENDED TREATMENT

There is no body of evidence available from controlled trials to indicate how long the patient with attention deficit hyperactivity disorder (ADHD) should be treated with CONCERTA. It is generally agreed, however, that pharmacological treatment of ADHD may be needed for extended periods.[1]

The effectiveness of CONCERTA for long-term use, i.e., for more than 7 weeks, has not been systemically evaluated in controlled trials. The physician who elects to use CONCERTA for extended periods in patients with ADHD should periodically re-evaluate the long-term usefulness of the drug for the individual patient with trials off medication to assess the patient's functioning without pharmacotherapy. Improvement may be sustained when the drug is temporarily or permanently discontinued.[1]

DOSE REDUCTION AND DISCONTINUATION

If paradoxical aggravation of symptoms or other adverse events occur, the dosage should be reduced, or, if necessary, the drug should be discontinued. If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued.[1]

COMBINING DOSAGE STRENGTHS

CONCERTA is available in 18, 27, 36 and 54 mg dosage strengths only.[1] If a healthcare provider wishes to prescribe CONCERTA at a dose outside of the four available strengths, they should ultimately determine how they prefer their patient receive the desired total daily dose. For example, CONCERTA may be prescribed as a once-a-day morning dose of one 18 mg and one 27 mg for a 45 mg daily dose or two CONCERTA 36 mg tablets for a 72 mg daily dose.

Modi et al (2000)[2] conducted a randomized, open-label, three-way cross-over study to evaluate the dose-ranging pharmacokinetics of multiple CONCERTA 18 mg systems used to establish 18 mg, 36 mg, and 54 mg doses in 35 healthy subjects, 18 to 45 years old. The comparison of the dose-normalized area under the concentration-time curve from

extrapolation to infinity (AUC_{inf}), maximum methylphenidate and α-phenyl-2-piperidine acetic acid plasma concentrations (C_{max}), and time to peak concentration (t_{max}) values of the regimens (1x18 mg, 2x18 mg, and 3x18 mg) demonstrated the dose-proportional pharmacokinetics of CONCERTA.

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 22 January 2025.

No citations were identified pertaining to dose equivalency or conversion to CONCERTA from another non-methylphenidate stimulant medication.

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.

2. Modi NB, Wang B, Noveck RJ, et al. Dose-proportional and stereospecific pharmacokinetics of methylphenidate delivered using an osmotic, controlled-release oral delivery system. *J Clin Pharmacol*. 2000;40(10):1141-1149.