Concerta

Pharmacology, Warnings, Pregnancy, Lactation, Side Effects, IV Compatibility, Dosage, Additional Dosage

Pharmacology (Top)

Pharmacology

Methylphenidate is a mild central nervous system stimulant.

The mechanism of action of methylphenidate has not been clearly defined. The drug has been reported to activate the brain stem arousal system and cortex to produce a stimulant effect. One study has reported that the drug works in the treatment of attention- deficit/hyperactivity disorder by increasing the levels of dopamine in the brain.

Methylphenidate has been approved by the FDA for use in the treatment of narcolepsy and attention-deficit disorder. (Use of methylphenidate in the treatment of attention-deficit disorder is intended as only part of a total treatment program that should also include other psychological, educational, and social measures.)

While not FDA approved indications, methylphenidate may be useful for the treatment of apathy, fatigue, inattention, or impulsivity associated with a variety of conditions such as Alzheimer's disorder, degenerative neurological illnesses, and in those who have suffered traumatic brain injury. Methylphenidate has been used to ameliorate opioid-induced somnolence, to augment the analgesic effects of opioids, to treat depression, and to improve cognitive function in patients with cancer. Methylphenidate has also shown efficacy in ameliorating cognitive, affective, and motor deficits in Parkinson's disease and in other neurological patients. Additional studies are required in order to establish efficacy.

Methylphenidate is listed as a Schedule II drug under the Federal Controlled Substances Act of 1970.

Pharmacokinetics

Methylphenidate is available for oral administration in immediate, sustained, and extended release formulations which include tablets, capsules, chewable tablets, and an oral solution. In addition, methylphenidate is available in a transdermal system.

Methylphenidate tablets for immediate release have been reported to be 28% bioavailable in fasting subjects and 31% bioavailable when administered with food. The manufacturer recommends administration of the drug "preferably 30 to 45 minutes before meals". However, at least one small study (n=7) which found that meals accelerate rather than impede the absorption of methylphenidate, has raised a question about that practice. The manufacturer has reported that the sustained release tablets are absorbed more slowly, but as extensively as the immediate release tablets. The manufacturer has also reported that after a single dose, the bioavailability of methylphenidate was reported to be unaffected by sprinkling the contents of a Metadate CD capsule on applesauce as compared to the intact capsule.

Following application of the transdermal patch, the onset of therapeutic effects occurs in approximately 2 hours and peak plasma levels are achieved in about 7 to 9 hours.

The plasma protein binding has been reported to be 16% in adults and 15% in children.

The volume of distribution at steady state was 2.65 and 1.8 L/kg for d- and l- methylphenidate , respectively, following a single 10 mg IV dose in patients with normal renal and hepatic function.

The total body clearance of d- and l- methylphenidate following a single 10 mg IV dose was 6.6 and 12.1 mL/min/kg, respectively, and the renal clearance for both enantiomers was 0.083 mL/min/kg. In theory, there is a possibility that the clearance of methylphenidate might be affected by urinary pH.

The average half-life has been reported to range from 2.0 to 2.6 hours, while the active metabolite, ritalinic acid has been reported to have a half-life of 4.8 hours. Following removal of the transdermal patch (application time 8 to 10 hrs) the mean half-life of d- methylphenidate was approximately 3 to 4 hours.

Methylphenidate is primarily metabolized via de-esterification to a carboxylic acid, ritalinic acid, its primary metabolite. None of the metabolites appear to have significant pharmacological activity. The cytochrome P450 system does not appear to be involved in the metabolism of methylphenidate.

In a clinical study involving adult subjects who received sustained release tablets reported by the manufacturer, plasma concentrations of ritalinic acid appeared to be greater in females than in males.

There are no data on the pharmacokinetic disposition of methylphenidate in patients with renal and/or liver dysfunction.

There are no data on the hemodialysis or peritoneal dialysis clearance of methylphenidate.

Warnings (Top)

(Severity: General Warning Exists)

Methylphenidate is considered contraindicated in patients with marked anxiety, tension, and agitation due to possible aggravation of these symptoms. In addition, the drug is considered contraindicated in patients with severe depression, schizophrenic symptoms, psychopathological personality structure, history of aggression, suicidal tendency, glaucoma, motor tics, family history or diagnosis of Tourette's syndrome, severe hypertension, anginal pectoris, cardiac arrhythmias, heart failure, recent myocardial infarction, and hyperthyroidism or thyrotoxicosis. Concomitant administration of methylphenidate with, or within 14 days of discontinuing treatment with, a monoamine oxidase inhibitor (MAOI) is considered contraindicated.

Hypersensitivity reactions, such as angioedema and anaphylactic reactions have been observed in patients treated with methylphenidate. Therefore, methylphenidate is contraindicated in patients known to be hypersensitive to methylphenidate or other components of the product.

One subject has been reported to have experienced erythema and edema at methylphenidate transdermal system application sites with concurrent urticarial lesions on the abdomen and legs resulting in treatment discontinuation. This subject was not transitioned to oral methylphenidate.

Although, methylphenidate is considered contraindicated in patients with glaucoma, the drug has been safely used in well-controlled open angle glaucoma with regular ophthalmologic exams, which include a check of intraocular pressure.

There are reports of sudden death associated with central nervous system (CNS) stimulant treatment administered at usual doses to pediatric patients with structural cardiac abnormalities or other serious heart problems. In addition, there are reports of sudden death, stroke, and myocardial infarction in adults receiving normal doses of stimulant drugs. Therefore, the use of stimulant products is not recommended in any patient with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac problems that may place them at increased vulnerability to the sympathomimetic effects of a stimulant drug. Individuals being considered for treatment should undergo a

physical examination to rule out the presence of cardiac disease and should undergo further cardiac assessment if such a condition is thought to be present. In addition a family medical history should be obtained, especially with regards to sudden death or ventricular arrhythmia. Patients who develop signs or symptoms of possible cardiac abnormalities during treatment with methylphenidate should immediately undergo a complete cardiac evaluation.

Stimulant medications cause an increase in heart rate and blood pressure. Therefore, caution is recommended if methylphenidate is to be used in patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, such as those with preexisting hypertension, heart failure, recent myocardial infarction, or hyperthyroidism. Blood pressure should be monitored at appropriate intervals in all patients taking methylphenidate, especially patients with hypertension.

There is a risk of sudden blood pressure increase during surgery. If surgery is planned, methylphenidate should not be taken on the day of the surgery.

Methylphenidate contains sucrose. Therefore, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not take this medicine.

There are reports of exacerbation of symptoms of behavior disturbance and thought disorder associated with the use of stimulants, especially in those individuals with preexisting psychotic disorder. Caution is recommended in administering stimulants to ADHD patients who have a known comorbid bipolar disorder due to possible induction of mixed/manic episode. It is recommended to screen all patients with comorbid depressive disorders for possible risk of bipolar disorder prior to initiating treatment with a stimulant.

There are reports of treatment emergent psychotic or manic symptoms occurring in pediatric patients without a history of psychotic illness or mania. These events have been reported in patients receiving stimulants at usual doses. If these symptoms occur, clinicians should consider the possible causal role of the medication. Discontinuation of the medication may be appropriate.

It is recommended to monitor patients for the appearance of, or worsening of, aggressive behavior or hostility.

Stimulants, including methylphenidate, may lower the seizure threshold irrespective of prior history of seizures and/or EEG abnormalities. It is recommended to discontinue methylphenidate if seizures are reported during treatment.

There are reports of visual disturbances, particularly difficulties in accommodation and blurring of vision, associated with stimulant treatment.

Data are inadequate to determine whether chronic administration of amphetamines may be associated with growth inhibition; therefore, growth should be monitored during treatment with alterations in treatment enacted as necessary.

Methylphenidate should be prescribed with caution to emotionally unstable patients, including patients with a history of drug dependence or alcoholism. These patients may have a tendency to increase the dosage they are using. Chronically abusive use may lead to marked tolerance and psychotic dependence with varying degrees of abnormal behavior. Frank psychotic episodes may occur (particularly with parenteral abuse). Drug withdrawal requires careful supervision as severe depression and the effects of chronic overactivity can be unmasked. Long-term follow up may be required.

It is recommended to avoid the use of methylphenidate for the treatment of depression or for the prevention or treatment of normal fatigue states.

It is recommended to periodically monitor complete blood count (CBC), differential, and platelet counts in patients receiving methylphenidate for a prolonged period of time.

The long-term effects of methylphenidate have not been well established.

Methylphenidate may lead to esophageal motility disorders.

When used for the treatment of attention deficit hyperactivity disorder, acute tolerance to methylphenidate has been reported.

Pregnancy (Top)

(Severity: Major Female Pregnancy Warning)

Methylphenidate has been assigned to pregnancy category C by the FDA. Adequate animal reproductive studies to establish the safe use of methylphenidate during pregnancy have not been conducted. There are no controlled data in human pregnancy. However, in the Michigan Medicaid Birth Defects Study involving 229,101 pregnancies from 1985 to 1992, there was one major cardiovascular birth defect reported out of 13 newborns who were exposed to methylphenidate during the first trimester. (One was expected.) (Written communication, Franz Rosa, MD, Food and Drug Administration, 1994) Methylphenidate is only recommended for use during pregnancy when benefit outweighs risk.

Lactation (Top)

(Severity: Minor Lactation Warning)

Methylphenidate is excreted into human milk. Adverse effects in the nursing infant are unlikely given a relatively low exposure. In one case, following a maternal daily dose of 40 mg twice daily, the milk-to-plasma ratio was 2.7. The relative infant dose was 0.2% of the weight- adjusted maternal dose and the absolute infant dose was 2.3 mcg/kg/day. Adverse effects were not detected in the infant. Caution is recommended if the drug is to be administered to a nursing woman.

In another case report, following a maternal dose of 5 mg in the morning and 10 mg at noon (immediate-release formulation), the mean milk/serum concentration ratio was 1.1 (range 0.8 to 1.6). The relative infant dose was 0.16% of the weight- adjusted maternal dose and the estimated absolute infant dose was 0.38 mcg/kg/day. . Adverse effects were not observed in the infant.

Side Effects (Top)

Nervous system

Nervous system side effects have frequently included tic. Convulsions and migraine have also been reported. Dizziness, drowsiness, dyskinesia, and Tourette's syndrome have been reported rarely. Neuroleptic malignant syndrome (NMS) and reversible ischemic neurological deficit have been reported very rarely.

Gastrointestinal

Gastrointestinal side effects have included nausea, vomiting, and abdominal pain. Nausea and vomiting appears to occur more frequently with the transdermal patch compared with oral administration.

Cardiovascular

Cardiovascular side effects have rarely included changes in blood pressure and pulse rate, cerebral arteritis, occlusion, angina, arrhythmia, palpitations, bradycardia, extrasystoles, ventricular extrasystoles, supraventricular tachycardia, Raynaud's phenomenon, and tachycardia. A case of cardiac arrest has also been reported. Additionally, cerebrovascular vasculitis, cerebral hemorrhages, and cerebrovascular accidents have been reported.

Other 1

Other side effects have rarely included headache, peripheral coldness, and auricular swelling. A withdrawal syndrome has been reported with the abrupt discontinuation of methylphenidate.

Hepatic

Hepatic side effects have rarely included abnormal liver function ranging from transaminase elevation to hepatic coma; however, causality has not been established. Increased blood alkaline phosphatase, increased blood bilirubin, and increased hepatic enzymes have also been reported.

Hematologic

Hematologic side effects have rarely included leukopenia, anemia, pancytopenia, thrombocytopenic purpura, and thrombocytopenia; however, causality has not been established.

Psychiatric

Psychiatric side effects have frequently included emotional lability and insomnia. Hallucination, mania, obsessive-compulsive disorder, and nervousness have also been reported. Emotional lability and insomnia appear to occur more frequently with the transdermal patch compared with oral administration. In patients wearing the transdermal patch for 12 hrs a day, the incidence of insomnia was 30%. Transient depressed mood and aggressive behavior have been reported rarely; however, causality has not been determined.

Dermatologic

Dermatologic side effects have included bullous conditions, exfoliative conditions, urticarias, pruritus, rashes, eruptions, erythema, and exanthemas. Scalp hair loss has been reported rarely; however, causality has not been determined.

Ocular

Ocular side effects have included visual disturbances, mydriasis, difficulties with accommodation, diplopia, and blurring of vision.

Respiratory

Respiratory side effects associated with methylphenidate topical patch have frequently included nasopharyngitis and nasal congestion.

Metabolic

Metabolic side effects have included anorexia, decreased appetite, and weight loss (primarily with prolonged therapy). Anorexia, decreased appetite, and weigh loss appears to occur more frequently with the transdermal

patch compared with oral administration. In patients wearing the transdermal patch for 12 hrs a day, the incidence of anorexia was 46%.

Local

Local side effects associated with the topical patch have included application site reactions such as bleeding, bruising, burn, burning, dermatitis, discharge, discoloration, discomfort, dryness, eczema, edema, erosion, erythema, excoriation, exfoliation, fissure, hyperpigmentation, hypopigmentation, induration, infection, inflammation, irritation, pain, papules, paresthesia, pruritus, rash, scab, swelling, ulcer, urticaria, vesicles, and warmth.

Hypersensitivity

Hypersensitivity side effects including generalized erythematous and urticarial rashes, allergic contact dermatitis, angioedema, and anaphylaxis have been reported.

Musculoskeletal

Musculoskeletal side effects including arthralgia, myalgia, and muscle twitching have been reported.

Most reported cases of neuroleptic malignant syndrome (NMS) involved patients who were treated concomitantly with other drugs associated with NMS.

Nervousness and insomnia may be controllable by reducing the dosage and omitting the drug in the afternoon or evening.

It is unclear whether CNS stimulant drugs (i.e., dextroamphetamine, methylphenidate, amphetamine-dextroamphetamine) have a role in either the development or worsening of tic disorders such as Tourette's syndrome. According to several case reports, use of CNS stimulant medications may have precipitated or exacerbated tic disorders in some patients with ADHD. Based on these cases, in Tourette's-susceptible patients, CNS stimulants may exacerbate motor and phonic tics that do not subside following discontinuation of the offending agent. In several controlled studies involving patients with ADHD and tic disorders, in the majority of patients, tics did not increase following use of CNS stimulants. In addition, controlled studies have not found that methylphenidate worsens motor tics in Tourette's syndrome nor has it increased tics in patients without Tourette's. However, it should be noted that tics were reported in 7% of patients using the methylphenidate patch compared to 1% to those taking it orally. Additional studies are required in order to clarify this association.

Methylphenidate topical patch is a dermal irritant. The resulting erythema does not typically cause an interference or discontinuation of treatment. However, further evaluation should be sought, if erythema, edema, and/or papules do not resolve or significantly reduce within 24 hours of patch removal. Consideration should be given to sensitization if erythema is accompanied by edema, papules, vesicles, or other evidence of more intense local reactions. Diagnosis of allergic contact dermatitis should include appropriate diagnostic testing.

One subject has been reported to have experienced erythema and edema at methylphenidate transdermal system application sites with concurrent urticarial lesions on the abdomen and legs resulting in treatment discontinuation. This subject was not transitioned to oral methylphenidate.

IV Compatibility

Dosage (Top)

Usual Adult Dose

Attention Deficit Disorder

Immediate release tablets including chewable tablets (Ritalin, Methylin, methylphenidate):
Initial Dose: 10 mg orally 2 or 3 times daily, preferably 30 to 45 minutes before breakfast and lunch, and a third dose between 2 and 4 PM, if necessary. For patients who have trouble sleeping at night while receiving methylphenidate, the last dose should be taken before 6 PM.
Maintenance dose: Doses may be increased weekly in increments of 5 to 10 mg up to a maximum of 60 mg per day. In some patients, 10 to 15 mg daily may suffice. For patients who have trouble sleeping at night while receiving methylphenidate, the last dose should be taken before 6 PM.

Sustained release tablets (Ritalin SR, Metadate ER):
Initial Dose: Methylphenidate is also available as a 10 mg and 20 mg sustained release tablets with a duration of action of approximately 8 hours. If dose of the sustained release tablet corresponds with the titrated dose of methylphenidate regular tablets (taken not more frequently than every 8 hours), then the sustained release tablets may be used instead of the regular tablets.
Maintenance Dose: The dose may be increased in weekly increments of 10 mg, up to a maximum of 60 mg/day, with the first dose taken before breakfast. Tablets should not be crushed or chewed.

Extended release capsules (Metadate CD):
Initial Dose: 20 mg orally once a day in the morning before breakfast.
Maintenance Dose: Doses may be increased weekly in increments of 20 mg up to a maximum of 60 mg once daily in the morning. The capsules should not be opened, chewed, or crushed.

Extended release capsules (Ritalin LA):
Initial Dose: 20 mg orally once a day in the morning before breakfast.
For patients already receiving methylphenidate:
If switching from immediate release tablets 10 mg twice a day or sustained release tablets 20 mg/day: 20 mg once daily.
If switching from immediate release tablets 15 twice a day: 30 mg once daily.
If switching from immediate release tablets 20 mg twice a day or sustained release tablets 40 mg/day: 40 mg once daily.
If switching from immediate release tablets 30 twice a day or sustained release tablets 60 mg/day: 60 mg once daily.
Maintenance Dose: Doses may be increased weekly in increments of 10 mg up to a maximum of 60 mg once daily in the morning. For patients unable to swallow the capsule, the contents may be sprinkled on applesauce and administered.

Extended release tablets (Concerta):
Initial: (Methylphenidate- naive patients) 18 mg once daily in the morning before breakfast.
For patients already receiving methylphenidate:
If switching from immediate release tablets 5 mg 2 or 3 times a day: 18 mg once daily.
If switching from immediate release tablets 10 mg 2 or 3 times a day: 36 mg once daily.
If switching from immediate release tablets 15 mg 2 or 3 times a day: 54 mg once daily.
If switching from immediate release tablets 20 mg 2 or 3 times a day: 72 mg once daily.

Maintenance: May increase by 18 mg increments at weekly intervals up to a maximum of 72 mg once daily in the morning before breakfast. Tablets should not be chewed, divided, or crushed.

Transdermal system (Daytrana):
Dose should be titrated to effect based on the following recommended titration schedule:

Week 1: 10 mg/9 hour patch daily
Week 2: 15 mg/9 hour patch daily
Week 3: 20 mg/9 hour patch daily
Week 4: 30 mg/9 hour patch daily
It is recommended to apply the patch topically to hip area 2 hours before an effect is needed and to remove the patch 9 hours after application. However, wear time should be individualized according to the needs and response of the individual patient.

Narcolepsy

Immediate release tablets (Ritalin, Methylin, methylphenidate):
Initial Dose: 10 mg orally 2 or 3 times daily, preferably 30 to 45 minutes before meals.
Maintenance dose: Doses may be increased weekly in increments of 5 to 10 mg up to a maximum of 60 mg per day. In some patients, 10 to 15 mg daily may suffice. For patients who have trouble sleeping at night while receiving methylphenidate, the last dose should be taken before 6 PM.

Sustained release tablets (Ritalin SR, Metadate ER):
Initial Dose: Methylphenidate is also available as a 10 mg and 20 mg sustained release tablets with a duration of action of approximately 8 hours. If dose of the sustained release tablet corresponds with the titrated dose of methylphenidate regular tablets (taken not more frequently than every 8 hours), then the sustained release tablets may be used instead of the regular tablets.
Maintenance Dose: The dose may be increased in weekly increments of 10 mg, up to a maximum of 60 mg/day, with the first dose taken before breakfast. Tablets should not be crushed or chewed.

Extended release capsules (Metadate CD):
Initial Dose: 20 mg orally once a day in the morning before breakfast.
Maintenance Dose: Doses may be increased weekly in increments of 20 mg up to a maximum of 60 mg once daily in the morning. The capsules should not be opened, chewed, or crushed.

Extended release tablets (Concerta):
Initial: (Methylphenidate- naive patients) 18 mg once daily in the morning before breakfast.
For patients already receiving methylphenidate:
If switching from immediate release tablets 5 mg 2 or 3 times a day: 18 mg once daily.
If switching from immediate release tablets 10 mg 2 or 3 times a day: 36 mg once daily.
If switching from immediate release tablets 15 mg 2 or 3 times a day: 54 mg once daily.
If switching from immediate release tablets 20 mg 2 or 3 times a day: 72 mg once daily.

Maintenance: May increase by 18 mg increments at weekly intervals up to a maximum of 72 mg once daily in the morning before breakfast. Tablets should not be chewed, divided, or crushed.

Depression

The manufacturers warn that methylphenidate should not be used for severe depression of either exogenous or endogenous origin.

Some studies have shown methylphenidate to be an effective adjuvant medication when used along with other standard antidepressant drug therapy (SSRIs or TCAs) for depression. However, no specific coadministered antidepressant medication or dose of methylphenidate has been generally accepted as optimum therapy. Therefore, no specific therapy or dose of methylphenidate can be recommended at this time for use in patients with depression.

Usual Pediatric Dose

Attention Deficit Disorder

6 years or older:
Immediate release tablets including chewable tablets (Ritalin, Methylin, methylphenidate):
Initial Dose: 2.5 to 5 mg orally twice daily, taken 30 to 45 minutes before breakfast and lunch.
Maintenance dose: Doses may be increased weekly in increments of 5 to 10 mg up to a maximum of 60 mg/day in 2 or 3 divided doses. For patients who have trouble sleeping at night while receiving methylphenidate, the last dose should be taken before 6 PM.

Sustained release tablets (Ritalin SR, Metadate ER):
Initial Dose: Methylphenidate is also available as a 10 mg and 20 mg sustained release tablets with a duration of action of approximately 8 hours. If dose of the sustained release tablet corresponds with the titrated dose of methylphenidate regular tablets (taken not more frequently than every 8 hours), then the sustained release tablets may be used instead of the regular tablets.
Maintenance Dose: The dose may be increased in weekly increments of 10 mg, up to a maximum of 60 mg/day, with the first dose taken before breakfast. Tablets should not be crushed or chewed.

Extended release capsules (Metadate CD):
Initial Dose: 20 mg orally once a day in the morning before breakfast.
Maintenance Dose: Doses may be increased weekly in increments of 20 mg up to a maximum of 60 mg once daily in the morning. Capsules should not be opened, chewed, or crushed.

Extended release tablets (Concerta):
Initial: (Methylphenidate- naive patients) 18 mg once daily in the morning before breakfast.
If switching from immediate release tablets 5 mg 2 or 3 times a day: 18 mg once daily.
If switching from immediate release tablets 10 mg 2 or 3 times a day: 36 mg once daily.
If switching from immediate release tablets 15 mg 2 or 3 times a day: 54 mg once daily.
If switching from immediate release tablets 20 mg 2 or 3 times a day: 72 mg once daily.
Maximum dose: 6 years to 12 years: 54 mg/day, over 12 years: 72 mg/day; do not exceed 2 mg/kg/day.
Maintenance: May increase by 18 mg increments at weekly intervals up to a maximum of 72 mg once daily in the morning before breakfast. Tablets should not be chewed, divided, or crushed.

Transdermal system (Daytrana):
Dose should be titrated to effect based on the following recommended titration schedule:
Week 1: 10 mg/9 hour patch daily
Week 2: 15 mg/9 hour patch daily
Week 3: 20 mg/9 hour patch daily
Week 4: 30 mg/9 hour patch daily
It is recommended to apply the patch topically to hip area 2 hours before an effect is needed and to remove the patch 9 hours after application. However, wear time should be individualized according to the needs and response of the individual patient.

Additional Dosage (Top)

Renal Dose Adjustments

Data not available

Liver Dose Adjustments

Data not available

Precautions

Methylphenidate is contraindicated in patients with glaucoma, motor tics, and Tourette's syndrome, and within 14 days of taking MAO inhibitors.

Periodic CBC, differential, and platelet counts are advised during prolonged therapy.

It is recommended to avoid use of stimulants, including methylphenidate, in patients with known structural cardiac abnormalities as cases of sudden death, primarily in children, have been reported.

Blood pressure and pulse should also be monitored at appropriate intervals in all patients taking methylphenidate, especially in patients with hypertension.

Data are inadequate to determine whether chronic administration of methylphenidate may be associated with growth inhibition; therefore, growth should be monitored during treatment.

Methylphenidate should be discontinued if no improvement is noted after appropriate dosage adjustment over one month.

Dialysis

Data not available

Other Comments

Drug treatment is not indicated in all cases of attention deficit disorder with hyperactivity and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe amphetamines should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics. Methylphenidate should be used as part of a comprehensive treatment program.

Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy.

If aggravation of symptoms or adverse effects are noted, dosage reduction or discontinuation may be indicated.

The transdermal patch should be placed on a different site each day, typically on the opposite hip.

Extended release formulations of methylphenidate should be swallowed whole and not crushed or chewed. It should be noted that Concerta tablets remain intact and exit the gastrointestinal tract as an empty shell.