

One Dose Lasts FROM HOME TO HOMEWORK™

PARENTS: Make sure you read the important information about Concerta™ (methylphenidate HCl) Extended-release Tablets below. To remove, just peel off.



For more information, call 1-888-440-7903 or visit www.concerta.net

Information for parents about Concerta™, the once-daily medication for children with Attention Deficit Hyperactivity Disorder (ADHD).

Please see accompanying important product information.

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Marketed by



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CONCERTA™
(methylphenidate HCl) Extended-release
tablets 18 mg, 36 mg

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The Challenge of ADHD

Attention Deficit Hyperactivity Disorder, also known as ADHD, is a condition that affects millions of children and adults. Today, ADHD affects approximately 3% to 5% of the school-age population, with boys diagnosed 3 to 4 times more than girls.

For a child with ADHD, it can mean feeling alone, and being unable to make and keep friends or participate in after-school activities, such as sports. Usually, academic performance is affected, too. Problems associated with ADHD may continue into adolescence and adulthood. And while many people are being treated for the disorder, many others are not receiving the proper care and attention they need.

Keep in mind that ADHD is a condition that affects not only the people who have it, but those around them as well. This guide provides information for parents and families about ADHD, how it is diagnosed, and an overview of treatment options, including a new medication called Concerta™ Extended-release Tablets.

How Is ADHD Diagnosed?

ADHD is not a new disorder. It was first observed among children in the early 1900s, and has been extensively studied for more than 50 years. Attention Deficit Disorder (ADD) may be the most well known name for the disorder, but is now considered a sub-classification of ADHD.

- In 1987, ADD was renamed Attention Deficit Hyperactivity Disorder to include not only inattention but also symptoms of hyperactivity-impulsivity

- ADHD is a medical condition
- Behavioral problems caused by upsetting events, especially among children, are not necessarily the signs of ADHD
- The emotional trauma of divorce, changing schools, or moving to a new area should not be mistaken for the symptoms of ADHD



Establishing a diagnosis of ADHD is complex and requires information obtained from multiple sources, such as parents, physicians, and teachers. The diagnosis is dependent on the report of characteristic behaviors observed by parents and teachers, and includes input from the child in addition to the physician's examination of the child.

As established by current medical practice, criteria for diagnosing ADHD require that symptoms of inattention and/or hyperactivity-impulsivity have persisted



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for at least 6 months and that they are more frequent and severe than typically observed in individuals at a comparable level of development.

Some symptoms of ADHD must have been present

Diagnostic Criteria for ADHD

Symptoms of Inattention

1. Often fails to give close attention to details or makes careless mistakes in schoolwork, work, or other activities
2. Often has difficulty sustaining attention in tasks or play activities
3. Often does not seem to listen when spoken to directly
4. Often does not follow through on instructions and fails to complete schoolwork, chores, or duties (not due to oppositional behavior or failure to understand instructions)
5. Often has difficulty organizing tasks and activities
6. Often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort (such as schoolwork or homework)
7. Often loses things necessary for tasks or activities (eg, toys, school assignments, pencils, books, or tools)
8. Is often easily distracted by extraneous stimuli
9. Is often forgetful in daily activities

Symptoms of Hyperactivity/Impulsivity

1. Often fidgets with hands or feet or squirms in seat
2. Often leaves seat in classroom or in other situations in which remaining seated is expected
3. Often runs about or climbs excessively in situations in which it is inappropriate (in adolescents or adults, may be limited to subjective feelings of restlessness)
4. Often has difficulty playing or engaging in leisure activities quietly
5. Is often "on the go" or often acts as if "driven by a motor"
6. Often talks excessively
7. Often blurts out answers before questions have been completed
8. Often has difficulty awaiting turn
9. Often interrupts or intrudes on others (eg, butts into conversations or games)

Source: Adapted from DSM-IV™ 1994.



before age 7, with some present in at least two settings (for instance, at school and at home). There must also be clear evidence of the symptoms affecting social or academic functioning.

While most people with ADHD have symptoms of both inattention and hyperactivity-impulsivity (see chart on previous page), one symptom pattern may predominate, resulting in three different subtypes:



- **Predominantly Hyperactive-Impulsive Type** is the subtype if six (or more) symptoms of hyperactivity-impulsivity (but fewer than six symptoms of inattention) have persisted for at least 6 months. Inattention may still be a significant clinical feature in such cases.
- **Predominantly Inattentive Type** is the subtype if six (or more) symptoms of inattention (but fewer than six symptoms of hyperactivity-impulsivity) have persisted for at least 6 months. This type is referred to sometimes as ADD.

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- **Combined Type** is the subtype if six (or more) symptoms of inattention and six (or more) symptoms of hyperactivity-impulsivity have persisted for at least 6 months. Most children and adolescents with ADHD have the Combined Type.

What Are the Treatment Options for ADHD?

There are two basic approaches for treatment and management that target the symptoms of ADHD. One is behavior management. The other is medication. The combination of these two main types of treatment is what is referred to as a **total treatment program**.

A total treatment program requires a coordinated effort among many people, including the child, the family, school personnel, physicians, and other health-care professionals. A total treatment program includes parent education and training in ADHD, behavior management techniques, an appropriate school environment, family counseling, and medication. The positive results that can be achieved make the extra effort all the more worthwhile.

Behavior management techniques are useful for parents and teachers, in home and school settings. Developing consistency across school, home, and community settings and among parents, teachers, and therapists is crucial to the success of behavioral treatment but can be a significant challenge to achieve.

Behavior management, as part of a total treatment program, is an important type of therapy for ADHD.

Some behavioral adjustments suggested by the American Medical Association (AMA) include:

- Asking your child's teacher to move your child to the front of the room



- Establishing daily checklists
- Focusing on success
- Reinforcing your child's self-esteem

Stimulants are the most frequently used medications for managing ADHD symptoms. These medications are effective in decreasing impulsivity and hyperactivity, and increasing attention. Approximately 70% to 80% of children and adults with ADHD respond positively to medications.



Many parents worry or feel guilty about medicating a child, but it's important to know that these medications have been used successfully and safely for more than 25 years in treating ADHD patients. If you see reports in the media about ADHD medications that concern you, you should discuss these issues with your child's physician. A physician is best qualified to help you decide what's right for your child and you.

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One Dose Lasts FROM HOME TO HOMEWORK™: Concerta™ Extended-release Tablets

Concerta™ is a medication developed for the treatment of ADHD in patients 6 years old and older. Concerta™ is intended to be part of an integrated, total treatment program that includes educational, behavioral, and social approaches.

Until Concerta™, there was no once-daily medication designed to work effectively for 12 hours. Some other forms of medication may require two or three doses per day to achieve the desired improvement in symptoms. Unlike other medications, Concerta™ uses a special delivery system called OROS® to supply a unique pattern of medication throughout the day and into the early evening hours. The OROS® system has been used for nearly 20 years in widely accepted prescription and over-the-counter medications, such as Sudafed® 24 Hour.*

Concerta™ is the first extended-release formulation of methylphenidate, the most widely prescribed medication for ADHD, designed to provide symptom control from morning through early evening with just one dose. Methylphenidate is a stimulant that has been used safely and effectively for decades to treat children with ADHD.

Concerta™ is designed to be taken just once a day, before a child leaves for school. The medication is then released gradually, improving attention and behavior, so a child can stay focused throughout the day.



*Sudafed® is a registered trademark of Warner-Lambert Company.

The once-a-day dosing of Concerta™ eliminates the need for in-school and after-school dosing. That's especially important for kids who have after-school activities and homework to do. Concerta™ can help to eliminate the feelings of embarrassment that children may feel having to take medication in the middle of the school day or during after-school activities.



How Should Concerta™ Be Taken?

Concerta™ should be taken in the morning, with or without breakfast. Concerta™ tablets must be swallowed whole with the aid of liquid, such as water, milk, or juice. Concerta™ must **NOT be chewed, divided, or crushed.**

The medication is contained within a non-absorbable shell designed to release the drug at a controlled rate. The tablet shell is eliminated from the body; patients should not be concerned if they occasionally notice something in their stool that looks like a tablet.

CONCERTA™ (methylphenidate HCl) Extended-release tablets 18 mg, 36 mg

What Are the Side Effects Associated With Concerta™ Extended-release Tablets?

In a controlled clinical study with patients using Concerta™, the most common side effects reported were headache (14%), upper respiratory tract infection (8%), stomach ache (7%), vomiting (4%), decreased appetite (4%), sleeplessness (4%), increased cough (4%), sore throat (4%), sinusitis (3%), and dizziness (2%).

This is not a complete list of possible side effects. Ask your doctor about other side effects. If any side effects develop, talk to your doctor.

Who Should Not Take Concerta™?

Concerta™ should NOT be taken by patients who:

- Have significant anxiety, tension, or agitation, since Concerta™ may make these conditions worse
- Are allergic to methylphenidate or any of the other ingredients in Concerta™
- Have glaucoma, an eye disease
- Have tics or Tourette's syndrome, or a family history of Tourette's syndrome
- Are taking a prescription monoamine oxidase inhibitor (MAOI). If you do not know if your prescription drug contains an MAOI, ask your doctor or pharmacist before taking this product.

Talk to the doctor if any of these conditions apply to your child. Please see attached important prescribing information.



Other Important Safety Information

Abuse of methylphenidate can lead to dependence. Tell the doctor if your child has ever abused or been dependent on alcohol or drugs, or if he or she is now abusing or dependent on alcohol or drugs.

Working Together, Overcoming the Challenge

Concerta™ is a proven advancement in the treatment of ADHD. Concerta™ can help, but it's only one part of a team effort. Families, teachers, physicians, and other



specialists all play key roles in the management of ADHD. Communication is extremely important. You should stay in touch regularly with your child's doctor, to help monitor his or her progress, whether taking medication or not. Together, you can make the right decisions for your child and help him or her to better manage the daily challenges of ADHD. Concerta™ can be an important part of your total treatment program.

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Information on the Web:

- American Medical Association
www.ama-assn.org
- Centers for Disease Control and Prevention
www.cdc.gov
- Children and Adults With Attention Deficit Disorder
www.chadd.org
- Concerta™ Product Information
www.concerta.net
- National Attention Deficit Disorder Association
www.add.org
- National Institutes of Health
www.nih.gov
- National Mental Health Association
www.nmha.org

Index of Terms

Attention Deficit Hyperactivity Disorder (ADHD) A medical condition characterized by inattention and/or hyperactivity-impulsivity. A broad range of symptoms is required for a diagnosis.

Attention Deficit Disorder (ADD) A subclassification of ADHD. Also known as Predominantly Inattentive Type ADHD.

Behavior Management The non-medical aspect of total treatment therapy. Usually involves parents, teachers, and therapists working with the child.

Combined Type ADHD A subtype of ADHD in which 6 or more symptoms of inattention and 6 or more symptoms of hyperactivity-impulsivity have persisted for at

least 6 months. The most common subtype of ADHD among children and adolescents.

Concerta™ An extended-release formulation of methylphenidate tablets for the treatment and management of ADHD. The newest form of methylphenidate is designed to last 12 hours with just one dose.

Methylphenidate The most commonly prescribed medication for treating and managing ADHD. It has been used safely and successfully among children and adults for 25 years.

OROS® Advanced Delivery System A unique delivery system that allows a Concerta™ tablet to release its medication in a controlled fashion over time after being swallowed, allowing for once-daily dosage.

Predominantly Hyperactivity-Impulsive Type ADHD A subtype of ADHD in which 6 or more symptoms of hyperactivity-impulsivity (but fewer than 6 symptoms of inattention) have persisted for at least 6 months.

Predominantly Inattentive Type ADHD A subtype of ADHD in which 6 or more symptoms of inattention (but fewer than 6 symptoms of hyperactivity-impulsivity) have persisted for at least 6 months. Also known as ADD.

Total Treatment Program A broad-based program of therapies embracing behavior management in combination with the appropriate use of medication.

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