

INFORMATION FOR PATIENTS TAKING FOCALIN™ XR, OR FOR THEIR PARENTS OR CAREGIVERS

Once Daily

Focalin^a XR
(dexamethylphenidate hydrochloride)
extended-release capsules



This information for patients or their parents or caregivers is about Focalin XR. Please read this before you start taking Focalin XR. Also, read the information you get each time you renew your prescription, in case anything has changed. Remember, this information does not take the place of your doctor's instructions. If you have any questions about this information or about Focalin XR, talk to your doctor or pharmacist.

WHAT IS FOCALIN XR?

Focalin XR is a once-a-day treatment for Attention Deficit Hyperactivity Disorder, or ADHD. Focalin XR contains the drug dexamethylphenidate (Focalin™), a central nervous system stimulant. Dexamethylphenidate hydrochloride is also found in methylphenidate which has been used to treat ADHD for more than 30 years. Focalin XR is available as 5, 10, and 20 mg extended-release capsules. Focalin XR is taken by mouth, once each day in the morning, before breakfast.

WHAT IS ATTENTION DEFICIT HYPERACTIVITY DISORDER?

ADHD has three main types of symptoms: inattention, hyperactivity, and impulsiveness. Symptoms of inattention include not paying attention, making careless mistakes, not listening, not finishing tasks, not following directions, and being easily distracted. Symptoms of hyperactivity and impulsiveness include fidgeting, talking excessively, running around at inappropriate times, and interrupting others. Some patients have more symptoms of hyperactivity and impulsiveness while others have more symptoms of inattentiveness. Some patients have all three types of symptoms.

Many people have symptoms like these from time to time, but patients with ADHD have these symptoms more than others their age. Symptoms must be present for at least 6 months to be certain of the diagnosis.

HOW DOES FOCALIN XR WORK?

When you take a Focalin XR capsule, half of the beads provide an immediate dose of dexamethylphenidate and the other half provide a delayed second release of the drug to continue to help lessen the symptoms of ADHD during the day. Dexamethylphenidate, the active ingredient in Focalin XR, helps increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

BEFORE FOCALIN XR TREATMENT

It is very important that ADHD be accurately diagnosed and that the need for medication be carefully assessed. It is important to remember that Focalin XR is only part of the overall management of ADHD. Parents, teachers, physicians and other professionals are part of a team that must work together.

Before Focalin XR treatment, your doctor should be made aware of any current or past physical or mental problems. Tell your doctor if there is a history of drug or alcohol abuse, depression, psychosis, epilepsy or seizure disorders, high blood pressure, glaucoma, facial tics (involuntary movements), or a family history of Tourette's syndrome.

Both your doctor and your pharmacist should also be informed of all medicines that you are taking, even if these drugs are not taken on a regular basis and are available without prescription. Your doctor will decide whether you can take Focalin XR with other medicines. Methylphenidate is known to interact with a number of other drugs. These include medicines to treat depression, such as monoamine oxidase inhibitors; to control seizures; and to thin blood. Sometimes these interactions may require a change in dosage, or occasionally stopping one of the drugs involved.

Tell your doctor if you are pregnant or nursing a baby.

WHO SHOULD NOT TAKE FOCALIN XR?

You should NOT take FOCALIN XR if:

- You have significant anxiety, tension, or agitation since FOCALIN XR may make these conditions worse.
- You are allergic to methylphenidate or any of the other ingredients in FOCALIN XR.
- You have glaucoma, an eye disease.
- You have tics or Tourette's syndrome, or a family history of Tourette's syndrome.
- You are taking a monoamine oxidase inhibitor, a type of drug, or have discontinued a monoamine oxidase inhibitor in the last 14 days.

Talk to your doctor if you believe any of these conditions apply to you.

HOW SHOULD I TAKE FOCALIN XR?

Take FOCALIN XR once each day in the morning.

Take the dose prescribed by your doctor. Your doctor may adjust the amount of drug you take until it is right for you. From time to time, your doctor may interrupt your treatment to check your symptoms while you are not taking the drug.

Focalin XR capsules may be taken at the same time as food or without food, although food may delay the absorption of Focalin XR. The Focalin XR capsule may be swallowed as whole capsules or the capsule may be opened and sprinkled on a small amount of applesauce. The capsule should not be crushed or chewed or its contents divided.

To sprinkle the contents of the capsule, open the capsule carefully and sprinkle the beads over a spoonful of applesauce. The mixture of drug and applesauce should be consumed immediately in its entirety. The drug and applesauce mixture should not be stored for future use.

If you also take antacids or drugs that suppress stomach acids, you should discuss with your physician or pharmacist how to take these drugs with Focalin XR.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF FOCALIN XR?

The most common side effects of Focalin XR in clinical trials in children over 6 years old were upset stomach, nausea, decreased appetite, headache and anxiety.

The most common side effects in clinical study of adults were dry mouth, dyspepsia, feeling jittery, dizziness, anxiety and throat pain.

Other side effects seen with dexamethylphenidate include vomiting, dizziness, sleeplessness, nervousness, tics, allergic reactions, increased blood pressure and psychosis (abnormal thinking or hallucinations).

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

Dependence

Abuse of dexamethylphenidate can lead to dependence. Tell your doctor if you have ever abused or been dependent on alcohol or drugs, or if you are now abusing or dependent on alcohol or drugs.

Blurred Vision

Tell your doctor if you have blurred vision when taking Focalin XR. This could be a sign of a serious problem.

Slower Growth

Slower growth (weight gain and/or height) has been reported with long-term use of methylphenidate in children. Your doctor will be carefully watching your height and weight. If you are not growing or gaining weight as your doctor expects, your doctor may stop your Focalin XR treatment.

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

WHAT MUST I DISCUSS WITH MY DOCTOR BEFORE TAKING FOCALIN XR?

Talk to your doctor *before* taking FOCALIN XR if you:

- Are being treated for depression or have symptoms of depression such as feelings of sadness, worthlessness, and hopelessness.

- Have motion tics (hard-to-control, repeated twitching of any parts of your body) or verbal tics (hard-to-control repeating of sounds or words).
- Have someone in your family with motion tics, verbal tics, or Tourette's syndrome.
- Have abnormal thoughts or visions, hear abnormal sounds, or have been diagnosed with psychosis.
- Have had seizures (convulsions, epilepsy) or abnormal EEGs (electroencephalograms).
- Have high blood pressure.
- Have an abnormal heart rate or rhythm.

Tell your doctor *immediately* if you develop any of the above conditions or symptoms while taking Focalin XR.

CAN I TAKE FOCALIN XR WITH OTHER MEDICINES?

Tell your doctor about *all* medicines that you are taking or intend to take. Your doctor should decide whether you can take Focalin XR with other medicines. These include:

- Other medicines that a doctor has prescribed.
- All medicines that you buy yourself without a prescription.
- Any herbal remedies that you may be taking.

Monoamine Oxidase (MAO) Inhibitors

You should not take Focalin XR with (MAO) inhibitors or within 14 days of stopping a MAO inhibitor.

Starting a New Medicine

While on Focalin XR, do not start taking a new medicine or herbal remedy before checking with your doctor.

Other Medicines You May Be Taking

Focalin XR may change the way your body reacts to certain medicines. These include medicines used to treat depression, prevent seizures, or prevent blood clots (commonly called "blood thinners"). Your doctor may need to change your dose of these medicines if you are taking them with Focalin XR.

Other Important Safety Information

Pregnancy and Nursing

Before taking Focalin XR, tell your doctor if you are pregnant or plan on becoming pregnant. If you take dexmethylphenidate, it may be in your breast milk. Tell your doctor if you are nursing a baby.

Overdose

Call a Poison Control Center or your doctor immediately if you take more than the amount of Focalin XR prescribed by your doctor.

WHAT ELSE SHOULD I KNOW ABOUT FOCALIN XR?

Focalin XR has not been studied in children under 6 years of age.

Focalin XR may be a part of your overall treatment for ADHD. Your doctor may also recommend that you have counseling or other therapy.

As with all medicines, never share Focalin XR with anyone else and take only the number of Focalin XR capsules prescribed by your doctor.

Focalin XR should be stored in a safe place at room temperature (between 59°-86°F). Do not store this medicine in hot, damp, or humid places. Keep the container of Focalin XR in a safe place, away from high-traffic areas where other people could have accidental or unauthorized access to the medication. Keep track of the number of capsules so that you will know if any are missing. Someone who has easy access to Focalin XR may be able to give the capsules to others or misuse the medication.

Keep out of the reach of children.

This leaflet summarizes the most important information about Focalin XR. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Focalin XR that is written for health professionals.

You can also call 1-888-NOW-NOVA (1-888-669-6682).

MAY 2005

PRINTED IN U.S.A.

T2005-35
T2005-32/T2005-35
5000378



Manufactured for
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936
By ELAN HOLDINGS INC.
Pharmaceutical Division
Gainesville, GA 30504

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