

15 REFERENCES

American Psychiatric Association. Diagnosis and Statistical Manual of Mental Disorders. 4th ed. Washington DC: American Psychiatric Association 1994.

16 HOW SUPPLIED/STORAGE AND HANDLING

5 mg Extended-Release Capsules (NDC 0078-0430-05) light-blue, (imprinted NVR D5) supplied in bottles of 100
10 mg Extended-Release Capsules (NDC 0078-0431-05) light caramel (imprinted NVR D10) supplied in bottles of 100
15 mg Extended-Release Capsules (NDC 0078-0493-05) green (imprinted NVR D15) supplied in bottles of 100
20 mg Extended-Release Capsules (NDC 0078-0432-05) white (imprinted NVR D20) supplied in bottles of 100
25 mg Extended-Release Capsules (NDC 0078-0608-05) light-blue and white (imprinted NVR D25) supplied in bottles of 100
30 mg Extended-Release Capsules (NDC 0078-0433-05) light caramel and white (imprinted NVR D30) supplied in bottles of 100
35 mg Extended-Release Capsules (NDC 0078-0609-05) light-blue and light caramel (imprinted NVR D35) supplied in bottles of 100
40 mg Extended-Release Capsules (NDC 0078-0434-05) green and white (imprinted NVR D40) supplied in bottles of 100
Store FOCALIN XR at 25°C (77°F), excursions permitted 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.]

Dispense in tight container (USP).

17 PATIENT COUNSELING INFORMATION

17.1 Information for Patients

Prescribers or other health professionals should inform patients, their families, and their caregivers about the benefits and risks associated with treatment with dexamethylphenidate and should counsel them in its appropriate use. A patient Medication Guide is available for Focalin XR. The prescriber or health professional should instruct patients, their families, and their caregivers to read the Medication Guide and should assist them in understanding its contents. Patients should be given the opportunity to discuss the contents of the Medication Guide and to obtain answers to any questions they may have. The complete text of the Medication Guide is reprinted at the end of this document.

Priapism

Advise patients, caregivers, and family members of the possibility of painful or prolonged penile erections (priapism). Instruct the patient to seek immediate medical attention in the event of priapism [see Warnings and Precautions (5.10)]

Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]

- Instruct patients beginning treatment with Focalin XR about the risk of peripheral vasculopathy, including Raynaud's Phenomenon, and associated signs and symptoms: fingers or toes may feel numb, cool, painful, and/or may change color from pale, to blue, to red
- Instruct patients to report to their physician any new numbness, pain, skin color change, or sensitivity to temperature in fingers or toes.
- **Instruct patients to call their physician immediately with any signs of unexplained wounds appearing on fingers or toes while taking Focalin XR**
- Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients.

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MEDICATION GUIDE

FOCALIN XR

(dexamethylphenidate hydrochloride) extended-release capsules CII

Read the Medication Guide that comes with FOCALIN XR before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with FOCALIN XR.

What is the most important information I should know about FOCALIN XR?

The following have been reported with use of dexamethylphenidate hydrochloride and other stimulant medicines.

1. Heart-related problems:

- **sudden death in patients who have heart problems or heart defects**
- **stroke and heart attack in adults**
- **increased blood pressure and heart rate**

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting FOCALIN XR.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with FOCALIN XR.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking FOCALIN XR.

2. Mental (Psychiatric) problems:

All Patients

- **new or worse behavior and thought problems**
- **new or worse bipolar illness**
- **new or worse aggressive behavior or hostility**

Children and Teenagers

- **new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms**

Tell your doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking FOCALIN XR, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

3. Circulation problems in fingers and toes [Peripheral vasculopathy, including Raynaud's phenomenon]: fingers or toes may feel numb, cool, painful, and/or may change color from pale, to blue, to red

- Tell your doctor if you have or your child has numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.
- **Call your doctor right away if you have or your child has any signs of unexplained wounds appearing on fingers or toes while taking Focalin XR**

What Is FOCALIN XR?

FOCALIN XR is a central nervous system stimulant prescription medicine. **It is used for the treatment of attention deficit and hyperactivity disorder (ADHD).** FOCALIN XR may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

FOCALIN XR should be used as a part of a total treatment program for ADHD that may include counseling or other therapies.

FOCALIN XR is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep FOCALIN XR in a safe place to prevent misuse and abuse. Selling or giving away FOCALIN XR may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs

Who should not take FOCALIN XR?

FOCALIN XR should not be taken if you or your child:

- are very anxious, tense, or agitated
- have an eye problem called glaucoma
- have tics or Tourette's syndrome, or a family history of Tourette's syndrome. Tics are hard to control repeated movements or sounds.
- are taking or have taken within the past 14 days an anti-depression medicine called a monoamine oxidase inhibitor or MAOI.
- are allergic to anything in FOCALIN XR. See the end of this Medication Guide for a complete list of ingredients.

FOCALIN XR should not be used in children less than 6 years old because it has not been studied in this age group.

FOCALIN XR may not be right for you or your child. Before starting FOCALIN XR tell your or your child's doctor about all health conditions (or a family history of) including:

- heart problems, heart defects, high blood pressure
- mental problems including psychosis, mania, bipolar illness, or depression
- tics or Tourette's syndrome
- seizures or have had an abnormal brain wave test (EEG)
- circulation problems in fingers or toes

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breast-feeding.

Can FOCALIN XR be taken with other medicines?

Tell your doctor about all of the medicines that you or your child take including prescription and nonprescription medicines, vitamins, and herbal supplements. FOCALIN XR and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking FOCALIN XR.

Your doctor will decide whether FOCALIN XR can be taken with other medicines.

Especially tell your doctor if you or your child takes:

- anti-depression medicines including MAOIs
- seizure medicines
- blood thinner medicines
- blood pressure medicines
- antacids
- cold or allergy medicines that contain decongestants

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while taking FOCALIN XR without talking to your doctor first.

How should FOCALIN XR be taken?

- **Take FOCALIN XR exactly as prescribed.** Your doctor may adjust the dose until it is right for you or your child.
- Take FOCALIN XR once each day in the morning. FOCALIN XR is an extended-release capsule. It releases medicine into your body throughout the day.
- FOCALIN XR can be taken with or without food. Taking FOCALIN XR with food may slow the time it takes for the medicine to start working.

- Swallow FOCALIN XR capsules whole with water or other liquids. **Do not chew, crush, or divide the capsules or the beads in the capsule.** If you or your child cannot swallow the capsule, open it and sprinkle the small beads of medicine over a spoonful of applesauce and swallow it right away without chewing.
- From time to time, your doctor may stop FOCALIN XR treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking FOCALIN XR. Children should have their height and weight checked often while taking FOCALIN XR. FOCALIN XR treatment may be stopped if a problem is found during these check-ups.
- **If you or your child takes too much FOCALIN XR or overdoses, call your doctor or poison control center right away, or get emergency treatment.**

What are possible side effects of FOCALIN XR?

See “**What is the most important information I should know about FOCALIN XR?**” for information on reported heart and mental problems.

Other serious side effects include:

- Serious allergic reactions (symptoms can be difficulty breathing, swelling of the face, neck and throat, rashes and hives, fever)
- slowing of growth (height and weight) in children
- seizures, mainly in patients with a history of seizures
- Painful and prolonged erections (priapism) have occurred with methylphenidate. If you or your child develop priapism seek medical help right away. Because of the potential for lasting damage, priapism should be evaluated by a doctor immediately.
- eyesight changes or blurred vision

Common side effects include:

- headache
- decreased appetite
- upset stomach
- dry mouth
- trouble sleeping
- dizziness
- anxiety
- nervousness

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

How should I store FOCALIN XR?

- Store FOCALIN XR in a safe place at room temperature, 59 to 86° F (15 to 30° C).
- **Keep FOCALIN XR and all medicines out of the reach of children.**

General information about FOCALIN XR

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FOCALIN XR for a condition for which it was not prescribed. Do not give FOCALIN XR to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about FOCALIN XR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about FOCALIN XR that was written for healthcare professionals. For more information about FOCALIN XR call 1-888-669-6682.

What are the ingredients in FOCALIN XR?

Active Ingredient: dexamethylphenidate hydrochloride

Inactive Ingredients: ammonio methacrylate copolymer, FD&C Blue #2 (5 mg, 15 mg, 25 mg, 35 mg, and 40 mg strengths), FDA/E172 yellow iron oxide (10 mg, 15 mg, 30 mg, 35 mg, and 40 mg strengths), gelatin, ink Tan SW-8010, methacrylic acid copolymer, polyethylene glycol, sugar spheres, talc, titanium dioxide, and triethyl citrate.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Focalin XR is a trademark of Novartis AG

SODAS[®] is a registered trademark of Elan Pharma International Ltd.

This product is covered by US patents including 5,837,284, 5,908,850, 6,228,398, 6,355,656, and 6,635,284.

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