NOW AVAILABLE: FOCALIN XR 30 MG

The Focalin XR® 30-mg capsule is now available and the Focalin XR label[1] no longer includes maximum daily dosing restrictions, so please process prescriptions for Focalin XR beyond 20 mg/day.

Prescriptions for Focalin XR 30 mg can be processed under NDC 0078-0433-05.

Doses above 30 mg/day in children and 40 mg/day in adults have not been studied and are not recommended. There is no clear finding of greater average benefits for higher doses compared with lower doses. Adverse events and discontinuations, however, were dose-related.

FOCALIN XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients aged 6 years and older. FOCALIN XR is indicated as an integral part of a total treatment program for ADHD that may include other measures (psychological, educational, social) for patients with this syndrome. Drug treatment may not be indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is often helpful. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

The effectiveness of FOCALIN XR for long-term use, ie, more than 7 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use FOCALIN XR for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient.

Please see reverse side for Important Safety Information.

Please see accompanying full Prescribing Information, including Medication Guide.

ONCE-DAILY
Focalin XR
dexmethylphenidate HCl
Extended-Release Capsules
5, 10, 15, 20, 30 mg

First line. Fast start. Full day.

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Important Safety Information

WARNING: DRUG DEPENDENCE

FOCALIN XR should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence, with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use, since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require follow-up.

FOCALIN XR is contraindicated in patients with marked anxiety, tension, and agitation, since the drug may aggravate these symptoms; in patients known to be hypersensitive to methylphenidate or other components of the product; in patients with glaucoma; in patients with motor tics or with a family history or diagnosis of Tourette syndrome; and during or within a minimum of 14 days following discontinuation of treatment with monoamine oxidase inhibitors (MAOIs), as hypertensive crisis may occur.

Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems. Sudden death, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses for ADHD. Stimulant products generally should not be used in patients with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious heart problems. Increased blood pressure and heart rate have been reported in patients taking FOCALIN XR. Patients should be assessed for preexisting cardiac conditions before starting FOCALIN XR.

Psychotic symptoms may be exacerbated in patients with psychotic disorders. Use with caution in patients with comorbid bipolar disorder. Treatment-emergent new psychotic or manic symptoms may occur without a prior history. Monitor for appearance or worsening of aggressive behavior or hostility.

Long-term suppression of growth has been reported with long-term use of stimulants. Growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

The threshold for seizures may be lowered. Difficulties with accommodation and blurring of vision have been reported with stimulant treatment. Periodic monitoring of CBC with differential is advised during prolonged therapy.

The most common adverse events (at least 5% and twice the incidence of placebo-treated patients) are dyspepsia, decreased appetite, headache, and anxiety for pediatric patients, and dry mouth, dyspepsia, headache, and anxiety for adult patients.

Reference: 1. Focalin XR [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2009.

Please see accompanying full Prescribing Information, including Medication Guide.

ONCE-DAILY Focalin XR® dexmethylphenidate HCl Extended-Release Capsules 5, 10, 15, 20, 30 mg

First line. Fast start. Full day.

NOVARTIS

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

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