ORIGINAL RESEARCH

Effects of a Tyramine-Enriched Meal on Blood Pressure Response in Healthy Male Volunteers Treated with Selegiline Transdermal System 6 mg/24 Hour

The Switching of Risperidone to Olanzapine in Elderly Nursing-Home Patients with Dementia: A Retrospective Study
S. Madhusoodanan and O. Bogunovic

REVIEW ARTICLES

Hyperfusion Syndromes: Insight into the Pathophysiology and Treatment of Hypertensive Encephalopathy
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Clinical Perspectives on the Combination of D-Cycloserine and Cognitive-Behavioral Therapy for the Treatment of Anxiety Disorder

Coenzyme Q10: A Review of Its Promise as a Neuroprotectant
A.J. Young, S. Johnson, D.C. Steffens, and P.M. Doraiswamy

PEARLS IN CLINICAL NEUROSCIENCE

Mind and Muscle: The Cognitive-Affective Neuroscience of Exercise
Important Safety Information

Adderall XR should not be used in patients with advanced arteriosclerosis; symptomatic cardiovascular disease; moderate to severe hypertension; hyperthyroidism; known hypersensitivity or idiosyncrasy to sympathomimetic amines; agitated states; glaucoma; a history of drug abuse; or during or within 14 days after treatment with monoamine oxidase inhibitors (MAOIs).

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 deaths, stroke, and myocardial infarction have been reported in adults taking stimulant drugs at usual doses in ADHD. Physicians should take a careful patient history, including family history, and physical exam, to assess the presence of cardiac disease. Patients who report symptoms of cardiac disease such as exertional chest pain and unexplained syncope should be promptly evaluated. Use with caution in patients whose underlying medical condition might be affected by increases in blood pressure or heart rate.

New psychosis, mania, aggression, growth suppression, and visual disturbances have been associated with the use of stimulants. Use with caution in patients with a history of psychosis, seizures or EEG abnormalities, bipolar disorder or depression. Growth monitoring is advised during prolonged treatment.

Amphetamines have a high potential for abuse. Administration of amphetamines for prolonged periods of time may lead to drug dependence. Particular attention should be paid to the possibility of subjects obtaining amphetamines for nontherapeutic uses or distribution to others and the drugs should be prescribed or dispensed sparingly. Misuse of amphetamine may cause sudden death and serious cardiovascular adverse events.

The most common adverse events in clinical studies of Adderall XR included: pediatric—loss of appetite, insomnia, abdominal pain, and emotional lability; adolescent—loss of appetite, insomnia, abdominal pain, and weight loss; adult—dry mouth, loss of appetite, insomnia, headache, and weight loss.

Please see Brief Summary of Prescribing Information, including Boxed Warning, on adjacent page.

*Adderall® is a registered trademark of Shire LLC, under license to Duramed Pharmaceuticals, Inc.

Shire US Inc.
Dysphagia™ (methylphenidate transdermal system)

**BRIEF SUMMARY:** Consult the full prescribing information for complete product information.

**INDICATIONS**

**Attention Deficit Hyperactivity Disorder (ADHD):** Dysphagia™ (methylphenidate transdermal system) is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children 6 years of age and older. It is intended for chronic use in the long-term management of the symptoms of ADHD.

**CONTRAINDICATIONS:**-Methylphenidate. Dysphagia™ is contraindicated in patients known to be hypersensitive to methylphenidate or to any of its components, or to microcrystalline cellulose, croscarmellose sodium, or other inactive ingredients. Dysphagia™ should be discontinued if contact sensitization is suspected.

**ADVERSE REACTIONS**

Skin Sensitization:

Contact sensitization should be corroborated by appropriate diagnostic testing.

Psychiatric Adverse Events

- Treatment-emergent adverse events that were reported with an incidence of 5% or greater for participants treated with methylphenidate and at a higher incidence than placebo include:
  - Hyperactivity-impulsivity
  - Agitation
  - Annoyance
  - Conduct disorder
  - Cyberphobia
  - Delusional thinking
  - Detachment
  - Depression
  - Discharge
  - Dizziness
  - Distress
  - Dysphoria
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Depression can recur many times.

Or not.

Extending the body of evidence

2-YEAR RECURRENCE PREVENTION

data for EFFEXOR XR

IMPORTANT TREATMENT CONSIDERATIONS

Suicidality in Children and Adolescents

Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of EFFEXOR XR or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. EFFEXOR XR is not approved for use in pediatric patients.

- EFFEXOR XR is contraindicated in patients taking monoamine oxidase inhibitors (MAOIs).
- Adult and pediatric patients taking antidepressants can experience worsening of their depression and/or the emergence of suicidality. Patients should be observed closely for clinical worsening and suicidality, especially at the beginning of drug therapy, or at the time of increases or decreases in dose. Anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania have been reported and may represent precursors to emerging suicidality. Stopping or modifying therapy should be considered especially when symptoms are severe, abrupt in onset, or not part of presenting symptoms.
- The development of potentially life-threatening serotonin syndrome may occur when EFFEXOR XR is coadministered with other drugs that may affect the serotonergic neurotransmitter systems. Concomitant use of EFFEXOR XR with MAOIs is contraindicated. If concomitant use of EFFEXOR XR with an SSRI, SNRI, or a triptan is clinically warranted, careful observation of the patient is advised. Concomitant use of EFFEXOR XR with tryptophan supplements is not recommended.
- Treatment with venlafaxine is associated with sustained increases in blood pressure (BP) in some patients. Postmarketing cases of elevated BP requiring immediate treatment have been reported. Pre-existing hypertension should be controlled. Regular BP monitoring is recommended.
- Mydriasis has been reported in association with venlafaxine; therefore, patients with raised intraocular pressure or those at risk of acute narrow-angle glaucoma (angle-closure glaucoma) should be monitored.
- Abrupt discontinuation or dose reduction has been associated with discontinuation symptoms. Patients should be counseled on possible discontinuation symptoms and monitored while discontinuing the drug; the dose should be tapered gradually.

Please see brief summary of Prescribing Information on adjacent pages.
**Premature Ejaculation (PE)**

- **Definition**: PE is defined as the inability to delay ejaculation long enough to bring the partner to orgasm.
- **Prevalence**: It is estimated that 30-50% of men have PE at some point in their lives.
- **Risk Factors**: Psychological factors, medical conditions, and substance use are common risk factors.
- **Treatment Options**: Behavioral therapy, medication therapy, and psychotherapy are effective treatments.
- **Complications**: PE can lead to relationship difficulties.

---

**Antidepressants and Pediatric Use**

- **Commonly reported adverse effects**: Decreased appetite, insomnia, hyperactivity, irritability, and agitation.
- **Risperidone and Venlafaxine**: The use of risperidone and venlafaxine in pediatric patients with ADHD has been associated with an increased risk of suicidal behavior and ideation.
- **Recommended precautions**: Close monitoring of patients who are started on therapy is recommended.
- **Discontinuation rates**: The discontinuation rates for anorexia were 1.0% in MDD studies. Treatment-emergent anorexia was more commonly reported for Effexor XR (8%) than placebo (2%) patients in GAD studies.
- **Cholesterol levels**: Measurement of serum cholesterol levels during long-term treatment is recommended.
- **Seizures**: Discontinue in any patient who develops seizures.
- **Bipolar Disorder**: Effexor XR is not approved for use in treating bipolar depression.

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**Drug Interactions**

- **CYP2D6 inhibitors**: These drugs can increase the risk of serotonin syndrome with the concomitant use of Effexor XR and triptans, tramadol, tryptophan supplements, or other 5-HT uptake inhibitors.
- **CYP3A4**: Venlafaxine slightly inhibited the CYP2D6-mediated metabolism of risperidone to 2-OH-desipramine.
- **Clomipramine**: Venlafaxine slightly inhibited the CYP3A4-mediated metabolism of clomipramine to desmethylclomipramine.
- **Haloperidol**: The 2-OH-desipramine AUCs increased by 2.5-4.5 fold, and the haloperidol Cmax increased 88%, but the haloperidol elimination half-life was unaffected by venlafaxine.

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**Pediatric Use**

- **Monitoring**: Families and caregivers should be advised to observe for the emergence of symptoms listed in the Medication Guide and to alert the prescriber if they occur.
- **DOSAGE AND ADMINISTRATION**: Treatment of children with Effexor XR should be started at the lowest possible effective dose (e.g., 37.5 mg for children aged 6-12 years and 50 mg for children aged 13-17 years).

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**Warnings**

- **Suicidal Risk**: There is an increased risk of suicidal behavior and ideation in pediatric patients being treated with antidepressants for MDD or other indications, both psychiatric and non-psychiatric, for children and adolescents.
- **Monitoring**: Patients should be monitored closely for the emergence of suicidal behavior and ideation during treatment.
- **Phenylketonuria**: Effexor XR contains phenylalanine; therefore, caution should be exercised when prescribing Effexor XR to phenylketonurics.

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**Mutagenesis**

- **Results**: Venlafaxine increased the frequency of chromosomal aberrations in mouse bone marrow cells and the frequency of sister chromatid exchange in human lymphocytes in vitro.
- **Human Data**: In a study, venlafaxine did not induced tumors in mice and rats given up to 1.7 times the maximum recommended human dose (MRHD) on a body surface area basis.

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**Teratogenicity**

- **Pregnancy**: Venlafaxine has been reported to be excreted in human milk. Because of the potential for serious adverse reactions in nursing infants, women should be advised not to breastfeed while taking Effexor XR.
- **Nonteratogenik effects**: Venlafaxine has been associated with an increased risk of seizure in children with ADHD, particularly those on high doses.

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**Drug Metabolism and Pharmacokinetics**

- **Venlafaxine**: Venlafaxine is metabolized by the cytochrome P450 (CYP) isoenzyme system, primarily CYP3A4.
- **ODV**: ODV is metabolized by CYP2D6.

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**Clinical Trials**

- **16-week, placebo-controlled study**: Both the Effexor XR (n=109) and the placebo (n=112) patients have shown improvements in the Clinical Global Impression-Improvement Scale, with 35% and 32% of patients respectively achieving a score of 1 (very much improved) or 2 (much improved).
- **DESCRIPTION OF TRADEMARKED USE**: The efficacy of Effexor XR in the treatment of major depressive disorder (MDD) has been established in placebo-controlled trials for MDD, GAD, and MDD, based on reports in the literature.
- **ADVERSE REACTIONS**: The most common adverse reactions reported in clinical trials include nausea, vomiting, flushing, dizziness, hyperthermia with features resembling neuroleptic malignant syndrome, and suicide attempt.
were similar to that observed in adult patients. The precautions for adults apply to pediatric patients.

Geriatric Use: Safety and effectiveness in the elderly population have been demonstrated.

Gastrointestinal: Greater sensitivity of some older individuals cannot be ruled out. Hypoestrogenism and SSRI antidepressants have been used, usually with adverse events leading to discontinuation. Concomitant use of Effexor XR and certain other medications may increase the risk of serotonin syndrome. Elderly patients should be monitored carefully for the development of serotonin syndrome.

Associated with Discontinuation of Treatment—

The most commonly reported adverse events are associated with discontinuation of treatment. These events have been reported for patients treated with Effexor XR in studies that compared Effexor XR with placebo. In the majority of cases, these events occurred within the first week of treatment.

Overdosage:

In overdosage as opposed to some characteristic(s) of venlafaxine-treated patients is not clear. Treatment should be symptomatic and supportive.

Toxicology:

Animal: In overdose situations, the most consistent signs of toxicity were sedation, vomiting, seizures, respiratory depression, and bradycardia. These signs were often associated with metabolic derangements including hyponatremia, hyperglycemia, and metabolic acidosis. These findings were consistent with a principal mode of toxicity from venlafaxine, serotonin syndrome, and death have been reported. Published retrospective studies report that

The FAQs provide a convenient and comprehensive source of information on Effexor XR, the treatment of depression, and other conditions associated with use of the medication. The FAQs cover a wide range of topics, from medication safety and side effects to patient support and education.

Wyeth Pharmaceuticals Inc., Philadelphia, PA 19101

The FAQs are a unique patient and education program that is designed to help you foster successful therapy.

Wyeth makes no warranties for the accuracy of this summary and does not accept liability for damages or losses that may result from errors or omissions in this summary.

The FAQs are updated periodically with new information and resources to help you provide the best care to your patients.
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SUPPLEMENT

Amyloid-Based Interventions in Alzheimer’s Disease

By Gary J. Kennedy, MD, Montefiore Medical Center; Todd E. Golde, MD, PhD, Mayo Clinic College of Medicine; Pierre N. Tariot, MD, University of Arizona College of Medicine; and Jeffrey L. Cummings, MD, University of California, Los Angeles

CME QUIZ

71 The quiz is CME-accredited by the Mount Sinai School of Medicine for 3.0 credit hours.

MISSION

CNS Spectrums’ editorial mission is to address relevant neuropsychiatric topics, including the prevalence of comorbid diseases among patients, and original research and reports that emphasize the profound diagnostic and physiologic connections made within the neurologic and psychiatric fields. The journal’s goal is to serve as a resource to psychiatrists and neurologists seeking to understand and treat disturbances of cognition, emotion, and behavior as a direct consequence of central nervous system disease, illness, or trauma.

This month’s issue of CNS Spectrums, as well as a host of educational resources, enduring materials, and archived issues, is available at www.cnsspectrums.com.
Too many times I've seen how quickly the devastating effects of bipolar disorder can impact my patients' lives—and the damage that each episode can cause.

Families torn apart.
Careers ravaged.
Relationships destroyed.

The stakes are high.

As a doctor, I fight every day to make sure that bipolar disorder will not win out.