



## Information Regarding Vyvanse® (lisdexamfetamine dimesylate) Loss of Exclusivity Frequently Asked Questions for Patients and Caregivers

Please see [Medication Guide](#) for VYVANSE, including **Boxed WARNING regarding Potential for Abuse and Dependence, and Important Safety Information on pages 2 and 3.**

The following information is intended to provide patients and caregivers information about Vyvanse and associated Takeda support programs.

### **1. When will generic versions of Vyvanse enter the market?**

Following the expiration of the FDA-granted regulatory market exclusivity for Vyvanse on August 24, 2023, generic versions of Vyvanse were eligible to seek FDA approval. Please refer to the FDA website for more information regarding availability of generic versions of brand-name medicines.

### **2. What does this mean for patients taking Vyvanse? Will patients' insurance still cover prescriptions for Vyvanse?**

Many insurance companies may continue to cover branded Vyvanse through December 31, 2023. However, the extent of ongoing coverage (formulary tier, coverage requirements, and patient costs) will vary by insurance company, government payor, and state. Please check your individual health plan as plan status and coverage may change without notice.

If your healthcare provider determines that branded Vyvanse is the right choice for you, they would need to specify "dispense as written" on the prescription, in accordance with local and state requirements.

### **3. Will Takeda continue to offer the patient assistance program (Help at Hand) for Vyvanse?**

The Help at Hand Program for Vyvanse will continue through the end of calendar year 2023. The last day to apply for the Help at Hand Program is October 16, 2023.

- All applications must be approved by 8:00 PM ET, Monday, October 16, 2023.
- Continuing the Help at Hand program through the end of the calendar year 2023 is intended to provide patients the time to work with their healthcare provider to determine the best course of care and treatment for them going forward.

### **4. Will Takeda continue to offer the Savings Card Program for Vyvanse?**

- For the Vyvanse Savings Card Program, the last day to enroll is October 16, 2023. Patients enrolled in the Savings Card Program can continue to use their savings card until December 31, 2023.
  - Per California state law, savings cards may not be used 3 months after generic availability.
  - Per Massachusetts state law, savings cards may not be used after generic availability.
- All requests for enrollment must be received by 11:59 PM ET, Monday, October 16, 2023.
- Continuing the Vyvanse Savings Card Program through the end of the calendar year 2023 is intended to provide patients the time to work with their healthcare provider to determine the best course of care and treatment for them going forward.

### **5. What if patients cannot afford generic options of Vyvanse?**

Patients who cannot afford any generic offerings for Vyvanse should work with their healthcare provider, their pharmacist, and their healthcare insurer to determine the best, affordable course of care and treatment to address their individual needs.

### **6. Will Takeda stop manufacturing Vyvanse?**

Takeda currently has no plans to stop manufacturing Vyvanse.

### **7. If you have any other questions, please call 1-877-TAKEDA-7 (1-877-825-3327).**

*Please see Important Safety Information on the next page.*

### **What is Vyvanse?**

Vyvanse is a prescription medicine used for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients 6 years and above, and for the treatment of moderate to severe binge eating disorder (B.E.D.) in adults. **Vyvanse is not for use in children under 6 years of age with ADHD.** Vyvanse is not for weight loss. It is not known if Vyvanse is safe and effective for the treatment of obesity. It is not known if Vyvanse is safe and effective for use in children with B.E.D.

### **IMPORTANT SAFETY INFORMATION**

**Abuse & Dependence. Vyvanse, other amphetamine containing medicines, and methylphenidate have a high chance for abuse and may cause physical and psychological dependence. Your healthcare provider (HCP) should check you or your child for signs of abuse and dependence before and during treatment with Vyvanse.**

Tell your HCP if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs. Your HCP can tell you more about the differences between physical and psychological dependence and drug addiction.

**Vyvanse is a federally controlled substance (CII) because it contains lisdexamfetamine dimesylate that can be a target for people who abuse prescription medicines or street drugs.** Keep Vyvanse in a safe place to protect it from theft. Never sell or give your Vyvanse to anyone else because it may cause death or harm to them and it is against the law.

### **Who should not take Vyvanse?**

**Do not take Vyvanse if you or your child are:**

- allergic to amphetamine products or any of the ingredients in Vyvanse. See [Medication Guide](#) for a list of ingredients.
- taking, or have stopped taking in the last 14 days, a medicine called a Monoamine Oxidase Inhibitor (MAOI).
- being treated with the antibiotic linezolid or intravenous methylene blue.

### **Vyvanse may cause serious side effects, including:**

- **Heart-related problems including:** sudden death, stroke, and heart attack in adults; sudden death in children who have heart problems or heart defects; increased blood pressure and heart rate. Your HCP should check you or your child carefully for heart problems before starting treatment with Vyvanse. Tell your HCP if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems. Your HCP should check your or your child's blood pressure and heart rate regularly during treatment with Vyvanse. **Call your HCP or go to the ER right away if you or your child have any signs of heart problems such as chest pain, shortness of breath, or fainting during treatment with Vyvanse.**
- **Mental (psychiatric) problems, including:** new or worse behavior and thought problems; new or worse bipolar illness; new psychotic symptoms (such as hearing voices, or seeing or believing things that are not real) or new manic symptoms. Tell your HCP about any mental problems you or your child have or about a family history of suicide, bipolar illness, or depression. **Call your HCP right away if you or your child have any new or worsening mental symptoms or problems during treatment with Vyvanse, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.**
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with Vyvanse. Vyvanse treatment may be stopped if your child is not growing or gaining weight.
- **Circulation problems in fingers and toes (Peripheral vasculopathy, including Raynaud's phenomenon).** Tell your HCP if you or your child's fingers or toes feel numb, cool, painful, change color from pale, to blue, to red, or if they are sensitive to temperature. Call your HCP right away if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with Vyvanse.
- **Serotonin Syndrome.** A potentially life-threatening problem called serotonin syndrome may happen when Vyvanse is taken with certain other medicines. Stop taking Vyvanse and call your HCP or go to the nearest hospital ER right away if you or your child develop any of the following signs and symptoms of serotonin

syndrome: agitation, flushing, coma, loss of coordination, dizziness, seeing or hearing things that are not real (hallucination), high body temperature (hyperthermia), fast heartbeat, seizures, sweating, confusion, tremors, stiff muscles, or muscle twitching, changes in blood pressure, nausea, vomiting, diarrhea.

**Before taking Vyvanse, tell your HCP about all medical conditions, including if you or your child:**

- are pregnant or plan to become pregnant. Vyvanse may harm the unborn baby.
- are breastfeeding or plan to breastfeed. Vyvanse passes into breast milk. You or your child should not breastfeed during treatment with Vyvanse. Talk to your HCP about the best way to feed the baby during treatment with Vyvanse.

**What are possible side effects of Vyvanse?**

**The most common side effects of Vyvanse in children 6 to 17 and adults with ADHD include:**

- loss of appetite (anorexia)
- decreased appetite
- diarrhea
- dry mouth
- trouble sleeping
- stomach pain
- anxiety
- weight loss
- dizziness
- irritability
- nausea
- vomiting

**The most common side effects of Vyvanse in adults with moderate to severe B.E.D. include:**

- dry mouth
- decreased appetite
- constipation
- anxiety
- trouble sleeping
- increased heart rate
- feeling jittery

***For additional safety information, click here for [Prescribing Information](#) and [Medication Guide](#) and discuss with your HCP.***

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**