

פברואר 2024

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

הריני להודיעכם כי העלון לרופא והעלון לצרכן של התכשיר עודכנו:

Vyvanse 30mg	ויאנס 30 מ"ג
Vyvanse 50 mg	ויאנס 50 מ"ג
Vyvanse 70 mg	ויאנס 70 מ"ג

capsules

הרכב:

Lisdexamfetamine dimesylate

התוויה מאושרת:

Vyvanse is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients ages 6 years and above.
Vyvanse is indicated for the treatment of Moderate to Severe Binge Eating Disorder (BED) for patient over 18 years.
Limitation of Use:
Vyvanse is not indicated or recommended for weight loss.
Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events.
The safety and effectiveness of Vyvanse for the treatment of obesity have not been established

בעלון לרופא נעשו עדכונים והחמרות בסעיפים הבאים:

5 WARNINGS AND PRECAUTIONS

5.1 ~~Potential for Abuse, Misuse and Dependence~~Addiction

~~CNS stimulants including VYVANSE, other amphetamine-containing products, and methylphenidate, have VYVANSE has~~ a high potential for abuse and dependence. ~~Assess the risk misuse. The use of abuse prior to prescribing and monitor for signs VYVANSE exposes individuals to the risks of abuse and dependence while on therapy misuse, which can lead to the development of a substance use disorder, including addiction. VYVANSE can be diverted for non-medical use into illicit channels or distribution [see Drug Abuse and Dependence (9.2, 9.3)].~~

5.2 ~~Serious Cardiovascular Reactions~~

~~Sudden Misuse and abuse of CNS stimulants, including VYVANSE, can result in overdose and death, stroke [see Overdosage (10)], and myocardial infarction have been reported in adults with CNS-stimulant treatment at recommended this risk is increase with higher doses or unapproved methods of administration, such as snorting or injection.~~

~~Before prescribing VYVANSE, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks and proper disposal of any unused drug. Advise patients to store VYVANSE in a safe place, preferably locked, and instruct patients to not give VYVANSE to anyone else. Throughout VYVANSE treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction.~~



5.2 Risks to Patients with Serious Cardiac Disease

Sudden death has been reported in ~~pediatric~~ patients with structural cardiac abnormalities ~~and/or~~ other serious ~~heart problems taking CNS cardiac disease who were treated with CNS~~ stimulants ~~at the recommended doses for ADHD dosage~~. Avoid **VYVANSE** use in patients with known structural cardiac abnormalities, cardiomyopathy, serious ~~heart cardiac~~ arrhythmia, coronary artery disease, ~~and/or~~ other serious ~~heart problems~~. ~~Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during VYVANSE treatment cardiac disease.~~

5.3 Increased Blood Pressure and Heart Rate Increases

CNS stimulants cause an increase in blood pressure (mean increase about 2 to 4 mm Hg) and heart rate (mean increase about 3 to 6 bpm). ~~Some patients may have larger increases.~~

Monitor all **VYVANSE-treated** patients for potential tachycardia and hypertension.

5.4 Psychiatric Adverse Reactions

Exacerbation of Pre-existing Psychosis

CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder.

Induction of a Manic Episode in Patients with Bipolar Disorder

CNS stimulants may induce a ~~mixed~~/manic ~~or mixed~~ episode ~~in patients with bipolar disorder~~. Prior to initiating **VYVANSE** treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, and depression).



New Psychotic or Manic Symptoms

CNS stimulants, at the recommended doses/dosage, may cause psychotic or manic symptoms, (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing VYVANSE. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in approximately 0.1% of CNS stimulant-treated patients compared to 0% in-of placebo-treated patients. If such symptoms occur, consider discontinuing VYVANSE.

5.5 Long-Term Suppression of Growth in Pediatric Patients

CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height) in pediatric patients treated with CNS stimulants, including VYVANSE.

In a 4-week, placebo-controlled trial of VYVANSE in pediatric patients ages 6 to 12 years old with ADHD, there was a dose-related decrease in weight in the VYVANSE groups compared to weight gain in the placebo group. Additionally, in studies of another stimulant, there was slowing of the increase in height [see *Adverse Reactions* (6.1)].

Closely monitor growth (weight and height) in VYVANSE-treated pediatric patients.

Patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted. VYVANSE is not approved for use in pediatric patients below 6 years of age [see *Use in Specific Populations* (8.4)].

5.6 Peripheral Vasculopathy, including Raynaud's Phenomenon

Stimulants, CNS stimulants, including VYVANSE, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include have included digital ulceration and/or soft

tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in post-marketing reports at different times and at the therapeutic doses/dosages of CNS stimulants in all age groups throughout the course of treatment. Signs and symptoms generally improve-improved after dosage reduction in-dose or discontinuation of drug. Careful observation for digital changes is necessary during treatment with stimulants. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for certain patients the CNS stimulant.

Careful observation for digital changes is necessary during VYVANSE treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for VYVANSE-treated patients who develop signs or symptoms of peripheral vasculopathy.

5.8 Motor and Verbal Tics, and Worsening of Tourette's Syndrome

CNS stimulants, including amphetamine, have been associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported [see *Adverse Reactions* (6.2)].

Before initiating VYVANSE, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor VYVANSE-treated patients for the emergence or worsening of tics or Tourette's syndrome, and discontinue treatment if clinically appropriate.



6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Known hypersensitivity to amphetamine products or other ingredients of VYVANSE [*see Contraindications (4)*]
- Hypertensive Crisis When Used Concomitantly with Monoamine Oxidase Inhibitors [*see Contraindications (4) and Drug Interactions (7.1)*]
- Drug Dependence, Abuse, Misuse and Addiction [*see Boxed Warning, Warnings and Precautions (5.1), and Drug Abuse and Dependence (9.2, 9.3)*]
- Risks to Patients with Serious Cardiovascular Reactions-Cardiac Disease [*see Warnings and Precautions (5.2)*]
- Increase Blood Pressure and Heart Rate Increases [*see Warnings and Precautions (5.3)*]
- Psychiatric Adverse Reactions [*see Warnings and Precautions (5.4)*]
- Long-Term Suppression of Growth in Pediatric Patients [*see Warnings and Precautions (5.5)*]
- Peripheral Vasculopathy, including Raynaud's phenomenon [*see Warnings and Precautions (5.6)*]
- Serotonin Syndrome [*see Warnings and Precautions (5.7)*]
- Motor and Verbal Tics, and Worsening of Tourette's Syndrome [*see Warnings and Precautions (5.8)*]

6.2 Postmarketing Experience

The following adverse reactions have been identified during ~~postapproval~~ post -approval use of VYVANSE. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events are as follows: cardiomyopathy, mydriasis, diplopia, difficulties with visual accommodation, blurred vision, eosinophilic hepatitis, anaphylactic reaction, hypersensitivity, dyskinesia, dysgeusia, motor and verbal tics, bruxism, depression, dermatillomania, alopecia, aggression, Stevens-Johnson Syndrome, chest pain, angioedema, urticaria, seizures, libido changes, frequent or prolonged erections, constipation, rhabdomyolysis and intestinal ischemia.



9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

VYVANSE contains lisdexamfetamine, a prodrug of amphetamine, a Schedule II controlled substance.

9.2 Abuse

~~CNS stimulants, including VYVANSE, other amphetamine-containing products, and methylphenidate have a high potential for abuse. VYVANSE has a high potential for abuse and misuse which can lead to the development of a substance use disorder, including addiction [see Warnings and Precautions (5.1)]. VYVANSE can be diverted for non-medical use into illicit channels or distribution.~~

Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect ~~Abuse is characterized by impaired control over drug use, compulsive use, continued use despite harm, and craving. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed.~~ Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence. ~~Both abuse and misuse may lead to addiction, and some individuals may develop addiction even when taking VYVANSE as prescribed.~~

~~Signs Misuse and symptoms abuse of lisdexamfetamine, a drug of amphetamine abuse may include cause increased heart rate, respiratory rate, or blood pressure, and/or sweating, dilated pupils, hyperactivity, restlessness, insomnia, decreased appetite, loss of coordination, tremors, flushed skin, vomiting, and/or abdominal pain. Anxiety, psychosis, hostility, aggression, and suicidal or homicidal ideation have also been seen. Abusers of observed with CNS stimulants may chew, snort, inject, abuse and/or use other unapproved routes of administration which misuse. Misuse and abuse of CNS stimulants, including VYVANSE, can result in overdose and death [see Overdosage (10)].~~

~~To reduce the abuse of CNS stimulants, including VYVANSE, assess the /, and this risk of abuse prior to prescribing. After prescribing, keep careful prescription records, educate patients and their families about abuse and on proper storage and disposal of CNS stimulants. Monitor for signs of abuse while on therapy, and re-evaluate the need for VYVANSE use. is increased with higher doses or unapproved methods of administration, such as snorting or injection.~~

9.3 Dependence

Physical Dependence

VYVANSE may produce physical dependence ~~from continued therapy.~~ Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by ~~a withdrawal syndrome produced by abrupt cessation, rapid signs and symptoms after abrupt discontinuation or a significant dose reduction, or administration of an antagonist.~~ a drug Withdrawal signs and symptoms after abrupt cessation discontinuation or dose reduction following prolonged high-dosage administration of CNS stimulants including VYVANSE include extreme fatigue and dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

VYVANSE may produce tolerance ~~from continued therapy.~~ Tolerance is a physiological state of adaptation in which exposure characterized by a reduced response to a specific drug after repeated administration (i.e., a higher dose of a drug results in a reduction of is required to produce the drug's desired and/or undesired effects over time, same effect that was once obtained at a lower dose).



10 OVERDOSAGE

Consult with a Certified Poison Control Center for up-to-date guidance and advice for treatment of overdose. Individual patient response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically at low doses.

Manifestations of amphetamine overdose include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia and rhabdomyolysis. Fatigue and depression usually follow the central nervous system stimulation. Serotonin syndrome has been reported with amphetamine use, including VYVANSE. Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.

Clinical Effects of Overdose

Overdose of CNS stimulants is characterized by the following sympathomimetic effects:

- Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac death. Takotsubo cardiomyopathy may develop.
- CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin syndrome, seizures, cerebral vascular accidents, and coma may occur.
- Life-threatening hyperthermia (temperatures greater than 104°F) and rhabdomyolysis may develop.

Overdose Management

Consider the possibility of multiple drug ingestion. The pharmacokinetic profile of VYVANSE should be considered when treating patients with overdose. Lisdexamfetamine and d-amphetamine are not dialyzable. Consider contacting a medical toxicologist for additional overdose management recommendations.

בעלון לצרכן נעשו עדכונים והחמרות בסעיפים הבאים:

2. לפני שימוש בתרופה

לפני הטיפול בוויאנס ספר לרופא או לרוקח אם:

- יש לך, לילדך או במשפחה היסטוריה של:
 - בעיות לב, מומי לב, מחלת לב, לחץ דם גבוה
 - בעיות נפשיות כגון פסיכוזה, מאניה, מחלה דו-קוטבית או דיכאון
 - בעיות בזרימת הדם באצבעות הידיים והרגליים
 - בעיות בכליות. הרופא עשוי להפחית את המינון
- תנועות או צלילים חוזרים (טיקים) או תסמונת טורט



4. תופעות לוואי

כמו בכל תרופה, השימוש ב-ויואנס עלול לגרום לתופעות לוואי בחלק מהמשתמשים. אל תיבהל למקרא רשימת תופעות הלוואי. יתכן ולא תסבול מאף אחת מהן.

יש לפנות מיד לרופא אם יש לך אחת מתופעות הלוואי **החמורות הבאות**:

- האטה בגדילה (גובה ומשקל) בילדים
- הפרעות בסירקולציה בכלי הדם באצבעות ובבהונות כפות הרגליים (מחלת כלי דם היקפיים, לרבות מחלת רנו). התסמינים עלולים לכלול:
 - תחושת נימול, קור, כאב באצבעות או בהונות כף הרגל
 - שינוי צבע מחיזור לכחול, או אדום באצבעות או בהונות כף הרגל
- [ספר לרופא שלך אם לך או לילדך יש חוסר תחושה, כאב, שינוי בצבע העור או רגישות](#)
- [לטמפרטורה באצבעות או בהונות.](#)
- [התקשר לרופא שלך מיד אם יש לך או לילדך סימנים של פצעים בלתי מוסברים המופיעים באצבעות או בהונות במהלך הטיפול ביוואנס.](#)
- [טיקים חדשים או החמרה בטיקים או בתסמונת טורט. ספר לרופא שלך אם אתה או ילדך סובלים מטיקים חדשים או החמרה בטיקים או מהחמרה של תסמונת טורט במהלך הטיפול ביוואנס.](#)

תופעות לוואי שכיחות של ויואנס במטופלים עם ADHD, (תופעות שמופיעות ב 10-1 משתמשים מתוך 100):

- חרדה
- בחילה
- הפחתת משקל
- שלשולים
- סחרחורת
- הקאות
- רעד
- פריחה
- שינוי במצב רוח
- חום
- ישנוניות או עייפות
- הרגשת עצבנות, חוסר מנוחה
- עלייה בלחץ דם
- הזעת יתר
- לא ניתן לקבל או לשמור על זקפה
- ירידה בחשק המיני
- פעלתנות יתר
- קצב לב מהיר
- קשיי נשימה
- טיקים
- אנורקסיה
- יובש בפה

- [דפיקות לב חזקות](#)
- [תוצאות ECG שאינן תקינות המראות ventricular hypertrophy](#)
- [היפראקטיביות פסיכומטורית](#)



תופעות לוואי שאינן שכיחות של ויואנס במטופלים עם ADHD, (תופעות שמופיעות ב 1-10 משתמשים מתוך 1000):

- דיבור יתר
- כאב בחזה
- כעס
- גרד עור כפייתי
- כאב ראש
- דיכאון
- פרנויה

תופעות לוואי נוספות בשכיחות לא ידועה:

- דפיקות לב חזקות, קרדיומיופטיה
- מיד־ראיזיס - הרחבת אישוני העיניים
- דיפלופיה, - ראייה כפולה
- ראייה מטושטשת או קושי בלהתמקד בעצמים
- דלקת כבד אאוזוניפילית - פגיעה בכבד ממקור אלרגי עם אפשרות לצהבת בעיניים ו/או העור
- תגובה אלרגית חמורה המאופיינת בירידה חדה בלחץ דם, קושי בנשימה, סרפדת /גירוד
- רגישות יתר
- תנועות לא רצוניות בלתי מבוקרות
- תחושת טעם רע בפה
- טיקים
- חריקת שיניים
- תחושת דיכאון או
- תוקפנות
- גרד עור כפייתי
- נשירת שיער
- תוקפנות
- תסמונת סטיבן ג'ונסון
- כאבים בחזה
- אנגיואדמה
- חרלת (אורטיקריה)
- פרכוסים
- שינוי בחשק המיני
- זקפה תכופה או מתמשכת
- עצירות
- תמס שריר (רבדומיוליזיס)
- איסכמיה במעיים

העלון לרופא והעלון לצרכן נמצאים בקישור וכן מפורסמים במאגר התרופות באתר משרד הבריאות וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בברכה,

מדיסון פארמה בע"מ

