



HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use LISDEXAMFETAMINE DIMESYLATE CAPSULES safely and effectively. See full prescribing information for LISDEXAMFETAMINE DIMESYLATE CAPSULES.

LISDEXAMFETAMINE DIMESYLATE capsules, for oral use, CI

Initial U.S. Approval: 2007

WARNING: ABUSE, MISUSE, AND ADDICTION
See full prescribing information for complete boxed warning.
Lisdexamfetamine dimesylate capsules has a high potential for abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Misuse and abuse of CNS stimulants, including lisdexamfetamine dimesylate capsules, can cause overdose and death (5.1, 9.2, 10).
• Before prescribing lisdexamfetamine dimesylate capsules, assess each patient's risk for abuse, misuse, and addiction.
• Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug.
• Throughout treatment, reassess each patient's risk and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

RECENT MAJOR CHANGES

Indications and Usage (1) 09/2025
Warnings and Precautions (5.1) 09/2025

INDICATIONS AND USAGE

Lisdexamfetamine dimesylate capsules are a central nervous system (CNS) stimulant indicated for the treatment of (1):

- Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older
- Moderate to severe binge eating disorder (BED) in adults

Limitations of Use:
• The use of lisdexamfetamine dimesylate capsules are not recommended in pediatric patients younger than 6 years of age because they had higher plasma exposure and a higher incidence of adverse reactions (e.g., weight loss) than patients 6 years and older at the same dosage (5.5, 8, 4).

• Lisdexamfetamine dimesylate capsules are not indicated for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of lisdexamfetamine dimesylate capsules for the treatment of obesity have not been established (6.2).

DOSEAGE AND ADMINISTRATION

Indicated Population	Initial Dose	Titration Schedule	Recommended Dose	Maximum Dose
ADHD (Adults and pediatric patients 6 years and older) (2,3)	30 mg every morning	10 mg or 20 mg weekly	30 mg to 70 mg per day	70 mg per day
BED (Adults) (2,3)	30 mg every morning	20 mg weekly	50 mg to 70 mg per day	70 mg per day

- Prior to treatment, assess for presence of cardiac disease (2,4)
- Severe renal impairment: Maximum dose is 50 mg/day (2,5)

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INDICATIONS AND USAGE

Lisdexamfetamine dimesylate capsules are indicated for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older [see Clinical Studies (14.1)].
- Moderate to severe binge eating disorder (BED) in adults [see Clinical Studies (14.2)].

Limitations of Use:
• The use of lisdexamfetamine dimesylate capsules are not recommended in pediatric patients younger than 6 years of age because they had higher plasma exposure and a higher incidence of adverse reactions (e.g., weight loss) than patients 6 years and older at the same dosage [see Warnings and Precautions (5.5), Use in Specific Populations (8.4)].

• Lisdexamfetamine dimesylate capsules are 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 lisdexamfetamine dimesylate capsules for the treatment of obesity have not been established [see Warnings and Precautions (5.5)].

2 DOSEAGE AND ADMINISTRATION

Prior to treating patients with lisdexamfetamine dimesylate capsules, assess:

- for the presence of cardiac disease (i.e., perform a careful history, family history of sudden death or ventricular arrhythmia, and physical exam) [see Warnings and Precautions (5.2)].
- the family history and clinically evaluate patients for motor or verbal tics or Tourette's syndrome before initiating lisdexamfetamine dimesylate capsules [see Warnings and Precautions (5.6)].

2.1 Pretreatment Screening

Take lisdexamfetamine dimesylate capsules orally in the morning with or without food; avoid afternoon doses because of the potential for insomnia. Lisdexamfetamine dimesylate capsules may be administered in one of the following ways:

- Information for lisdexamfetamine dimesylate capsules.
- Open capsules, empty and mix the entire contents with yogurt, water, or orange juice. If the contents of the capsule include any compacted powder, a spoon may be used to break apart the powder. The contents should be mixed until completely dispersed. Consume the entire mixture immediately. It should not be stored. The active ingredient dissolves completely once dispersed; however, a film containing the inactive ingredients may remain in the glass or container once the mixture is consumed.

Lisdexamfetamine dimesylate capsules can be substituted with lisdexamfetamine dimesylate chewable tablets on a unit per unit/mg per mg basis (for example, 30 mg capsules for 30 mg chewable tablet) [see Clinical Pharmacology (12.3)].

Do not take anything less than one capsule per day. A single dose should not be divided.

2.2 Dosage for Treatment of ADHD

The recommended starting dosage in adults and pediatric patients 6 years and older is 30 mg once daily in the morning. Dosage may be adjusted in increments of 10 mg to 20 mg at approximately weekly intervals up to maximum recommended dosage of 70 mg once daily [see Clinical Studies (14.1)].

2.3 Dosage for Treatment of Moderate to Severe BED in Adults

The recommended starting dosage in adults is 30 mg once daily to be titrated in increments of 20 mg at approximately weekly intervals to achieve the recommended target dose of 50 mg to 70 mg once daily. The maximum recommended dosage is 70 mg once daily [see Clinical Studies (14.2)].

2.4 Dosage for Treatment of Moderate to Severe BED in Adults

The recommended starting dosage in adults is 30 mg once daily to be titrated in increments of 20 mg at approximately weekly intervals to achieve the recommended target dose of 50 mg to 70 mg once daily. The maximum recommended dosage is 70 mg once daily [see Clinical Studies (14.2)].

2.5 Dosage in Patients with Renal Impairment

In patients with severe renal impairment (GFR 15 to <30 mL/min/1.73 m²), the maximum dosage should not exceed 50 mg once daily. In patients with end stage renal disease (ESRD, GFR <15 mL/min/1.73 m²), the maximum recommended dosage is 30 mg once daily [see Use in Specific Populations (8.6)].

2.6 Dosage Modifications due to Drug Interactions

Agents that alter urinary pH can impact urinary excretion and alter blood levels of amphetamine. Acidifying agents (e.g., ascorbic acid) increase blood levels, while alkalinizing agents (e.g., sodium bicarbonate) decrease blood levels. Adjust lisdexamfetamine dimesylate capsules dosage accordingly [see Drug Interactions (7)].

3 DOSAGE FORMS AND STRENGTHS

Lisdexamfetamine dimesylate capsules:

- Capsules 10 mg: Hard Gelatin Capsule Shell Size "3" Pink Opaque Cap imprinted with AC in Black ink and Pink Opaque body imprinted with 10 in black ink filled with White to Off-white powder.
- Capsules 20 mg: Hard Gelatin Capsule Shell Size "3" Ivory Opaque Cap imprinted with AC in Black ink and Ivory Opaque body imprinted with 20 in black ink filled with White to Off-white powder.
- Capsules 30 mg: Hard Gelatin Capsule Shell Size "3" Orange Opaque Cap imprinted with AC in Black ink and White Opaque body imprinted with 30 in black ink filled with White to Off-white powder.
- Capsules 40 mg: Hard Gelatin Capsule Shell Size "3" Blue Opaque Cap imprinted with AC in Black ink and White Opaque body imprinted with 40 in black ink filled with White to Off-white powder.
- Capsules 50 mg: Hard Gelatin Capsule Shell Size "3" Blue Opaque Cap imprinted with AC in Black ink and White Opaque body imprinted with 50 in black ink filled with White to Off-white powder.
- Capsules 60 mg: Hard Gelatin Capsule Shell Size "2" Aqua Blue Opaque Cap imprinted with AC in Black ink and Aqua Blue Opaque body imprinted with 60 in black ink filled with White to Off-white powder.
- Capsules 70 mg: Hard Gelatin Capsule Shell Size "2" White Opaque Cap imprinted with AC in Black ink and Blue Transparent body imprinted with 70 in black ink filled with White to Off-white powder.

4 CONTRAINDICATIONS

Lisdexamfetamine dimesylate capsules are contraindicated in patients with:

- Known hypersensitivity to amphetamine products or other ingredients of lisdexamfetamine dimesylate capsules. Anaphylactic reactions, including anaphylaxis, angioedema, and urticaria have been observed in postmarketing reports [see Adverse Reactions (6.2)].
- Patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs (including MAOIs such as linezolid or intravenous methylxanthine base), because of an increased risk of hypertensive crisis [see Warnings and Precautions (5.7) and Drug Interactions (7)].

5 WARNINGS AND PRECAUTIONS

5.1 Abuse, Misuse, and Addiction

Lisdexamfetamine dimesylate capsules has a high potential for abuse and misuse. The use of lisdexamfetamine dimesylate capsules exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. Lisdexamfetamine dimesylate capsules can be diverted for non-medical use into illicit channels or distribution [see Abuse, Misuse, and Addiction (5.1), Warnings and Precautions (5.2), Misuse and Abuse of CNS Stimulants, including lisdexamfetamine dimesylate capsules, can result in overdose and death [see Overdose (10)], and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection].

Before prescribing lisdexamfetamine dimesylate capsules, 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. Throughout lisdexamfetamine dimesylate capsules treatment, reassess each patient's risk for 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 patients with structural cardiac abnormalities or other serious cardiac disease who were treated with CNS stimulants at the recommended ADHD dosage. Avoid lisdexamfetamine dimesylate capsules use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease.

5.3 Increased Blood Pressure and Heart Rate

CNS stimulants cause an increase in blood pressure (mean increase about 2 to 4 mm Hg) and heart rate (mean increase about 3 to 10 bpm). Some patients may have larger increases.

Monitor all lisdexamfetamine dimesylate capsules-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 manic or mixed episode. Prior to initiating lisdexamfetamine dimesylate capsules treatment, screen patients for risk factors for developing a manic episode (i.e., comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, and depression).

New Psychotic or Manic Symptoms
New psychotic or manic symptoms, at the recommended 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. 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% of placebo-treated patients. If such symptoms occur, consider discontinuing lisdexamfetamine dimesylate capsules.

5.5 Long-Term Suppression of Growth in Pediatric Patients

Lisdexamfetamine dimesylate capsules are not approved for use and are not recommended in pediatric patients below 6 years of age [see Use in Specific Populations (8.4)].

CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients.

In a 4-week, placebo-controlled trial of lisdexamfetamine dimesylate capsules in pediatric patients ages 6 to 12 years old with ADHD, there was a dose-related decrease in weight in the lisdexamfetamine dimesylate capsules 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 lisdexamfetamine dimesylate capsules-treated pediatric patients. Patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

5.6 Peripheral Vasculopathy, including Raynaud's Phenomenon

CNS stimulants, including lisdexamfetamine dimesylate capsules, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, acuteque have included digital ulcers and/or soft tissue breakdown. Effects of peripheral vasculopathy, including Raynaud's phenomenon, were observed in post-marketing reports and at the therapeutic dosages of CNS stimulants in all ages throughout the course of treatment. Signs and symptoms generally improved after dosage reduction or discontinuation of the CNS stimulant.

Careful observation for digital changes is necessary during lisdexamfetamine dimesylate capsules treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for lisdexamfetamine dimesylate capsules-treated patients who

• End stage renal disease (ESRD): Maximum dose is 30 mg/day (2,5)

DOSEAGE FORMS AND STRENGTHS

- Capsules: 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg (3)

CONTRAINDICATIONS

- Known hypersensitivity to amphetamine products or other ingredients in lisdexamfetamine dimesylate capsules (4)
- Use with monoamine oxidase (MAO) inhibitor, or within 14 days of the last MAOI inhibitor dose (4, 7, 1)

WARNINGS AND PRECAUTIONS

- Risks to Patients with Serious Cardiac Disease: Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease (5, 2)
- Increased Blood Pressure and Heart Rate: Monitor blood pressure and heart rate (5, 3)
- Psychiatric Adverse Reactions: Prior to initiating lisdexamfetamine dimesylate capsules, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing lisdexamfetamine dimesylate capsules (4)
- Long-Term Suppression of Growth in Pediatric Patients: Closely monitor growth (height and weight) in pediatric patients. Patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted (5, 5)
- Peripheral Vasculopathy, including Raynaud's phenomenon: Careful observation for digital changes is necessary during lisdexamfetamine dimesylate capsules treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy (5, 6)
- Serotonin Syndrome: Increased risk when co-administered with serotonergic agents (e.g., SSRIs, SNRIs, tricyclics), but also during overdose situations. If it occurs, discontinue lisdexamfetamine dimesylate capsules and initiate supportive treatment, and discontinue the serotonergic agent (5, 7)
- Motor and Verbal Tics, and Worsening of Tourette's Syndrome: Before initiating lisdexamfetamine dimesylate capsules, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor patients for the emergence or worsening of tics or Tourette's syndrome. Discontinue treatment if clinically appropriate (5, 8)

ADVERSE REACTIONS

Most common adverse reactions (incidence >5% and at a rate at least twice placebo) in pediatric patients ages 6 to 17 years, and/or adults with ADHD were anorexia, anxiety, decreased appetite, decreased weight, diarrhea, dizziness, dry mouth, irritability, insomnia, nausea, upper abdominal pain, and vomiting (6, 1)

Most common adverse reactions (incidence >5% and at a rate at least twice placebo) in adults with BED were dry mouth, insomnia, decreased appetite, increased heart rate, constipation, feeling jittery, and anxiety (8, 1)

Most common adverse reactions (incidence >5% and at a rate at least twice placebo) reported in adults were dry mouth, insomnia, decreased appetite, increased heart rate, constipation, feeling jittery, and anxiety (8, 1)

For reported SUSPECTED ADVERSE REACTIONS, contact Camber Pharmaceuticals, Inc., at 1-866-495-8330 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Acidifying and Alkalinizing Agents: Agents that alter urinary pH can alter blood levels of amphetamine. Acidifying agents decrease and alkalinizing agents increase blood levels of amphetamine. Adjust lisdexamfetamine dimesylate capsules dosage accordingly (2, 6, 7, 1)

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm (8, 1)
- Lactation: Breastfeeding is contraindicated (8, 2)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 05/2026

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17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

17.1 Patient Counseling Information

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at baseline and 12 months were 60.9 and 47.2, respectively. In a 4-week controlled trial of lisdexamfetamine dimesylate capsules in pediatric patients ages 13 to 17 years, mean weight loss from baseline to endpoint was -2.7, -4.3, and -4.8 lbs., respectively.

• Increased Blood Pressure and Heart Rate: Monitor blood pressure and heart rate (5, 3)

• Psychiatric Adverse Reactions: Prior to initiating lisdexamfetamine dimesylate capsules, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing lisdexamfetamine dimesylate capsules (4)

• Long-Term Suppression of Growth in Pediatric Patients: Closely monitor growth (height and weight) in pediatric patients. Patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted (5, 5)

• Peripheral Vasculopathy, including Raynaud's phenomenon: Careful observation for digital changes is necessary during lisdexamfetamine dimesylate capsules treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy (5, 6)

• Serotonin Syndrome: Increased risk when co-administered with serotonergic agents (e.g., SSRIs, SNRIs, tricyclics), but also during overdose situations. If it occurs, discontinue lisdexamfetamine dimesylate capsules and initiate supportive treatment, and discontinue the serotonergic agent (5, 7)

• Motor and Verbal Tics, and Worsening of Tourette's Syndrome: Before initiating lisdexamfetamine dimesylate capsules, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor patients for the emergence or worsening of tics or Tourette's syndrome. Discontinue treatment if clinically appropriate (5, 8)

• Abuse, Misuse, and Addiction: Before prescribing lisdexamfetamine dimesylate capsules, assess each patient's risk for abuse, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout lisdexamfetamine dimesylate capsules treatment, reassess each patient's risk for abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction [see Warnings and Precautions (5.1), Abuse, Misuse, and Addiction (5.1), Warnings and Precautions (5.2), Misuse and Abuse of CNS Stimulants, including lisdexamfetamine dimesylate capsules, can result in overdose and death [see Overdose (10)], and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection].

• Risks to Patients with Serious Cardiac Disease: Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmia, coronary artery disease, or other serious cardiac disease (5, 2)

• Increased Blood Pressure and Heart Rate: Monitor blood pressure and heart rate (5, 3)

• Psychiatric Adverse Reactions: Prior to initiating lisdexamfetamine dimesylate capsules, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing lisdexamfetamine dimesylate capsules (4)

• Long-Term Suppression of Growth in Pediatric Patients: Closely monitor growth (height and weight) in pediatric patients. Patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted (5, 5)

• Peripheral Vasculopathy, including Raynaud's phenomenon: Careful observation for digital changes is necessary during lisdexamfetamine dimesylate capsules treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy (5, 6)

• Serotonin Syndrome: Increased risk when co-administered with serotonergic agents (e.g., SSRIs, SNRIs, tricyclics), but also during overdose situations. If it occurs, discontinue lisdexamfetamine dimesylate capsules and initiate supportive treatment, and discontinue the serotonergic agent (5, 7)

• Motor and Verbal Tics, and Worsening of Tourette's Syndrome: Before initiating lisdexamfetamine dimesylate capsules, assess the family history and clinically evaluate patients for tics or Tourette's syndrome. Regularly monitor patients for the emergence



14 CLINICAL STUDIES

14.1 Attention Deficit Hyperactivity Disorder (ADHD)
Pediatric Patients Ages 6 to 12 Years with ADHD
A double-blind, randomized, placebo-controlled, parallel-group study (Study 1) was conducted in pediatric patients ages 6 to 12 years (N=290) who met DSM-IV criteria for ADHD (either the combined type or the hyperactive-impulsive type). Patients were randomized to receive final doses of 30 mg, 50 mg, or 70 mg of lisdexamfetamine dimesylate capsules or placebo once daily in the morning for a total of four weeks of treatment. All patients receiving lisdexamfetamine dimesylate capsules were initiated on 30 mg for the first week of treatment. Patients assigned to the 50 mg and 70 mg dose groups were titrated by 20 mg per week until they achieved their assigned dose. The primary efficacy outcome was change in Total Score from baseline to endpoint in investigator ratings on the ADHD Rating Scale (ADHD-RS), an 18-item questionnaire with a score range of 0-54 points that measures the core symptoms of ADHD which includes both hyperactive/impulsive and inattentive subscales. Endpoint was defined as the last post-randomization treatment week (i.e., Weeks 1 through 4) for which a valid score was obtained. All lisdexamfetamine dimesylate capsules dose groups were superior to placebo in the primary efficacy outcome. Mean effects at all doses were similar; however, the highest dose (70 mg/day) was numerically superior to both lower doses (Study 1 in Table 6). The effects were maintained throughout the day based on parent ratings (Conners' Parent Rating Scale) in the morning (approximately 10 am), afternoon (approximately 2 pm), and early evening (approximately 6 pm).

A double-blind, placebo-controlled, randomized, crossover design, analog classroom study (Study 2) was conducted in pediatric patients ages 6 to 12 years (N=52) who met DSM-IV criteria for ADHD (either the combined type or the hyperactive-impulsive type). Following a 3-week open-label dose optimization with Adderall XR[®], patients were randomly assigned to continue their optimized dose of Adderall XR (10 mg, 20 mg, or 30 mg) or lisdexamfetamine dimesylate capsules (30 mg, 50 mg, or 70 mg) or placebo once daily in the morning for 1 week each treatment. Efficacy assessments were conducted at 1, 2, 3, 4, 5, 6, 8, 10, and 12 hours post-dose using the Swanson, Kojan, Agler, M.F., Fynn, and Pelham Department scores (SKAMP-DS), a 4-item subscale of the SKAMP with scores ranging from 0 to 24 points that measures department problems leading to classroom disruptions. A significant difference in patient behavior, based upon the average of investigator ratings on the SKAMP-DS across the 8 assessments were observed between patients who received lisdexamfetamine dimesylate capsules compared to patients when they received placebo (Study 2 in Table 6). The drug effect reached statistical significance from hours 2 to 12 post-dose, but was not significant at 1 hour.

A second double-blind, placebo-controlled, randomized, crossover design, analog classroom study (Study 3) was conducted in pediatric patients ages 6 to 12 years (N=129) who met DSM-IV criteria for ADHD (either the combined type or the hyperactive-impulsive type). Following a 4-week open-label dose optimization with lisdexamfetamine dimesylate capsules (30 mg, 50 mg, or 70 mg), patients were randomly assigned to continue their optimized dose of lisdexamfetamine dimesylate capsules or placebo once daily in the morning for 1 week each treatment. A significant difference in patient behavior, based upon the average of investigator ratings on the SKAMP-Department scores across all 7 assessments conducted at 1, 2, 5, 5.0, 7.5, 10.0, 12.0, and 13 hours post-dose, were observed between patients who received lisdexamfetamine dimesylate capsules compared to patients when they received placebo (Study 3 in Table 6, Figure 4).

Pediatric Patients Ages 13 to 17 Years with ADHD
A double-blind, randomized, placebo-controlled, parallel-group study (Study 4) was conducted in pediatric patients ages 13 to 17 years (N=314) who met DSM-IV criteria for ADHD. In this study, patients were randomized to a 1:1:1:1 ratio to a daily morning dose of lisdexamfetamine dimesylate capsules (50 mg, 70 mg, or 90 mg/day) or placebo for the first 4 weeks of treatment. All patients receiving lisdexamfetamine dimesylate capsules were initiated on 50 mg for the first week of treatment. Patients assigned to the 50 mg and 70 mg dose groups were titrated by 20 mg per week until they achieved their assigned dose. The primary efficacy outcome was defined as the last post-randomization treatment week (i.e., Weeks 1 through 4) for which a valid score was obtained. All lisdexamfetamine dimesylate capsules dose groups were superior to placebo in the primary efficacy outcome (Study 4 in Table 6).
Pediatric Patients Ages 18 to 17 Years, Short-Term Treatment (Study 5)
A double-blind, randomized, placebo- and active-controlled parallel-group, dose-optimization study (Study 5) was conducted in pediatric patients ages 6 to 17 years (N=336) who met DSM-IV criteria for ADHD. In this eight-week study, patients were randomized to a daily morning dose of lisdexamfetamine dimesylate capsules (30, 50 or 70 mg/day), an active control, or placebo (1:1:1). The study consisted of a 2-week Double-blind Evaluation Period (consisting of a 4-week Dose-Optimization Period followed by a 3-week Dose-Maintenance Period), and a 1-week Washout and Follow-up Period. During the Dose-Optimization Period, subjects were titrated until an optimal dose, based on tolerability and investigator's judgment, was reached. Lisdexamfetamine dimesylate capsules showed significantly greater efficacy than placebo. The placebo-adjusted mean reduction from baseline in the ADHD-RS IV total score was 18.6. Subjects on lisdexamfetamine dimesylate capsules also showed greater improvement on the Clinical Global Impression-Improvement (CGI-I) rating scale compared to subjects on placebo (Study 5 in Table 6).

Pediatric Patients Ages 18 to 17 Years, Maintenance Treatment in ADHD
Maintenance of Efficacy Study (Study 6) – A double-blind, placebo-controlled, randomized withdrawal study was conducted in pediatric patients ages 6 to 17 years (N=276) who met the diagnosis of ADHD (DSM-IV criteria). A total of 276 patients were enrolled into the study. Patients were randomized to 40 mg of lisdexamfetamine dimesylate capsules or placebo for the first 4 weeks of treatment. All patients receiving lisdexamfetamine dimesylate capsules for at least 26 weeks prior to being assessed for entry into the randomized withdrawal period. Eligible patients had to demonstrate treatment response as defined by CGI-S <3 and Total Score on the ADHD-RS <22. Patients that maintained a treatment response for 2 weeks at the end of the open label treatment period were eligible to be randomized to ongoing treatment with the same dose of lisdexamfetamine dimesylate capsules (N=78) or switched to placebo (N=78) during the double-blind phase. Patients were observed for relapse (treatment failure) during the 6-week double-blind phase. A significantly lower proportion of treatment failures occurred among lisdexamfetamine dimesylate capsules subjects (15.8%) compared to placebo (67.5%) at endpoint of the randomized withdrawal period. The endpoint measurement was defined as the last post-randomization treatment week at which a valid ADHD-RS Total Score and CGI-S were observed. Treatment failure was defined as a >50% increase (worsening) in the ADHD-RS Total Score and a >2-point increase in the CGI-S score compared to scores at entry into the double-blind randomized withdrawal phase. Subjects who withdrew from the randomized withdrawal period and who did not provide efficacy data at their last on-treatment visit were classified as treatment failures (Study 6, Figure 5).

Adults: Short-Term Treatment in ADHD
A double-blind, randomized, placebo-controlled, parallel-group study (Study 7) was conducted in adults ages 18 to 55 (N=420) who met DSM-IV criteria for ADHD. In this study, patients were randomized to receive final doses of 30 mg, 50 mg, or 70 mg of lisdexamfetamine dimesylate capsules or placebo for a total of four weeks of treatment. All patients receiving lisdexamfetamine dimesylate capsules were initiated on 30 mg for the first week of treatment. Patients assigned to the 50 mg and 70 mg dose groups were titrated by 20 mg per week until they achieved their assigned dose. The primary efficacy outcome was change in Total Score from baseline to endpoint in investigator ratings on the ADHD Rating Scale (ADHD-RS). Endpoint was defined as the last post-randomization treatment week (i.e., Weeks 1 through 4) for which a valid score was obtained. All lisdexamfetamine dimesylate capsules dose groups were superior to placebo in the primary efficacy outcome (Study 7 in Table 6).

The second study was a multi-center, randomized, double-blind, placebo-controlled, cross-over, modified analog classroom study (Study 8) of lisdexamfetamine dimesylate capsules to simulate a workplace environment in 142 adults ages 18 to 55 who met DSM-IV criteria for ADHD. There was a 4-week open-label, dose optimization phase with lisdexamfetamine dimesylate capsules (30 mg/day, 50 mg/day, or 70 mg/day) in the morning. Patients were then randomized to one of two treatment sequences: 1) lisdexamfetamine dimesylate capsules (optimized dose) followed by placebo, each for one week, or 2) placebo followed by lisdexamfetamine dimesylate capsules, each for one week. Efficacy assessments occurred at the end of each week, using the Permanent Product Measure of Performance (PERMP), a skill-adjusted math test that measures attention in ADHD. PERMP total score results from the sum of the number of math problems attempted plus the number of math problems answered correctly. Lisdexamfetamine dimesylate capsules treatment, compared to placebo, resulted in a statistically significant improvement in attention across all post-dose time points, as measured by average PERMP total scores over the course of one assessment day, as well as at each time point measured. The PERMP assessments were administered at pre-dose (<0.5 hours) and at 2, 4, 8, 10, 12, and 14 hours post-dose (Study 8 in Table 6, Figure 6).

Adults: Maintenance Treatment in ADHD
A double-blind, placebo-controlled, randomized withdrawal design study (Study 9) was conducted in adults ages 18 to 55 (N=123) who had a documented diagnosis of ADHD or met DSM-IV criteria for ADHD. At study entry, patients must have had documentation of lisdexamfetamine dimesylate capsules for a minimum of 6 months and had to demonstrate treatment response as defined by Clinical Global Impression Severity (CGI-S) <3 and Total Score on the ADHD-RS <22. ADHD-RS Total Score is a measure of core symptoms of ADHD. The CGI-S score assesses the clinician's impression of the patient's current illness state and ranges from 1 (not at all) to 5 (extremely). Patients that maintained a treatment response at Week 3 of the open label treatment phase (N=116) were eligible to be randomized to ongoing treatment with the same dose of lisdexamfetamine dimesylate capsules (N=58) or switched to placebo (N=58) during the double-blind phase. Patients were observed for relapse (treatment failure) during the 6-week double-blind phase. The efficacy endpoint was the proportion of patients with treatment failure during the double-blind phase. Treatment failure was defined as a >50% increase (worsening) in the ADHD-RS Total Score and a >2-point increase in the CGI-S score compared to scores at entry into the double-blind phase. Maintenance of efficacy for patients treated with lisdexamfetamine dimesylate capsules was demonstrated by the significantly lower proportion of patients with treatment failure (9%) compared to patients receiving placebo (75%) at endpoint during the double-blind phase (Study 9, Figure 7).

Study Number (Age range)	Primary Endpoints	Treatment Group	Mean Baseline Score (SD)	LS Mean Change from Baseline (SE)	Placebo-subtracted Difference (95% CI)
Study 1 (6-12 years)	ADHD-RS-IV	Lisdexamfetamine dimesylate capsules (30 mg/day)	43.2 (8.7)	-21.8 (1.6)	-15.6 (-19.9, -11.2)
		Lisdexamfetamine dimesylate capsules (50 mg/day)	43.6 (8.7)	-23.4 (1.6)	-17.2 (-21.5, -12.9)
		Placebo	42.4 (7.1)	-8.2 (1.6)	-20.5 (-24.8, -16.2)
Study 2 (6-12 years)	Average SKAMP-DS	Lisdexamfetamine dimesylate capsules (30, 50 or 70 mg/day)	-	0.8 (0.1)*	-0.9 (-1.1, -0.7)
		Placebo	-	1.7 (0.1)*	-
		Placebo	-	0.7 (0.1)*	-0.7 (-0.9, -0.6)
Study 3 (6-12 years)	Average SKAMP-DS	Lisdexamfetamine dimesylate capsules (30, 50 or 70 mg/day)	-	0.7 (0.3)*	1.4 (0.1)*
		Placebo	-	1.8 (1.3)	-
		Placebo	-	37.3 (8.3)	-21.1 (1.3)
Study 4 (13-17 years)	ADHD-RS-IV	Lisdexamfetamine dimesylate capsules (30 mg/day)	37.3 (8.3)	-20.7 (1.3)	-7.9 (-11.4, -4.5)
		Lisdexamfetamine dimesylate capsules (50 mg/day)	37.3 (8.3)	-20.7 (1.3)	-7.9 (-11.4, -4.5)
		Placebo	38.7 (7.1)	-12.8 (1.3)	-
Study 5 (6-17 years)	ADHD-RS-IV	Lisdexamfetamine dimesylate capsules (30, 50 or 70 mg/day)	40.7 (7.3)	-24.3 (1.2)	-18.6 (-21.5, -15.7)
		Placebo	41.0 (7.1)	-5.7 (1.1)	-
		Placebo	40.5 (8.2)	-16.2 (1.1)	-8.0 (-11.5, -4.6)
Study 7 (18-55 years)	ADHD-RS-IV	Lisdexamfetamine dimesylate capsules (30 mg/day)	40.8 (7.3)	-17.4 (1.0)	-9.2 (-12.6, -5.7)
		Lisdexamfetamine dimesylate capsules (50 mg/day)	41.0 (8.0)	-18.1 (1.1)	-10.4 (-13.8, -6.9)
		Placebo	39.4 (8.4)	-8.2 (1.4)	-
Study 8 (18-55 years)	Average PERMP	Lisdexamfetamine dimesylate capsules (30, 50 or 70 mg/day)	261.1 (86.2)*	312.9 (8.6)*	23.4 (15.6, 31.2)
		Placebo	281.4 (75.0)*	289.5 (8.6)*	-
		Placebo	281.4 (75.0)*	289.5 (8.6)*	-

SD: standard deviation; SE: standard error; LS Mean: least-squares mean; CI: confidence interval.
*Difference (drug minus placebo) is least-squares mean change from baseline.
†Pre-dose SKAMP-DS was not collected.
‡Pre-dose SKAMP-DS (Study 3) or PERMP (Study 8) total score, averaged over both periods.
§Mean for SKAMP-DS (Study 2) and 3 or PERMP (Study 8) total score, averaged over all sessions of the treatment day, rather than change from baseline.
*Doses statistically significantly superior to placebo.

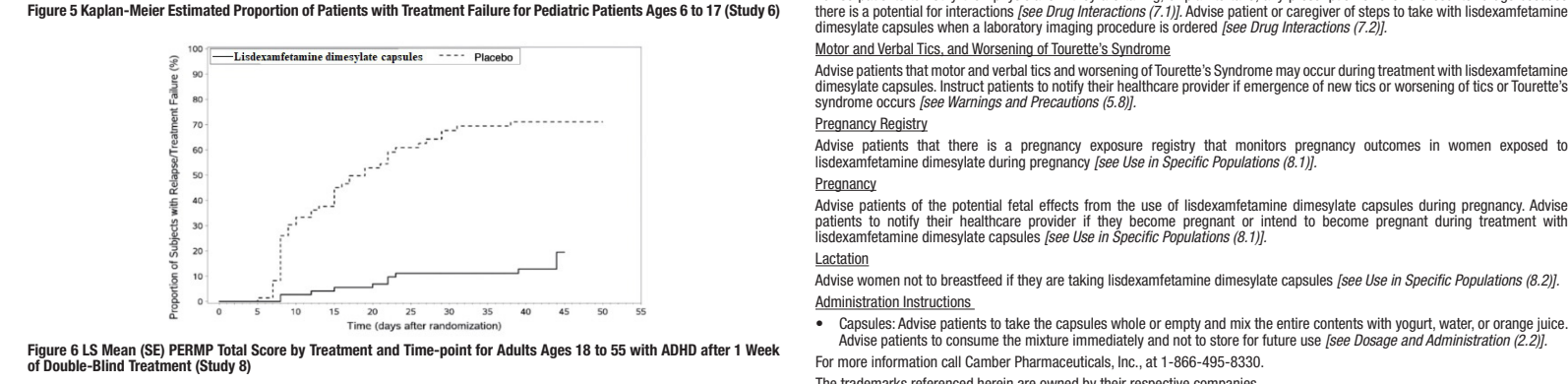
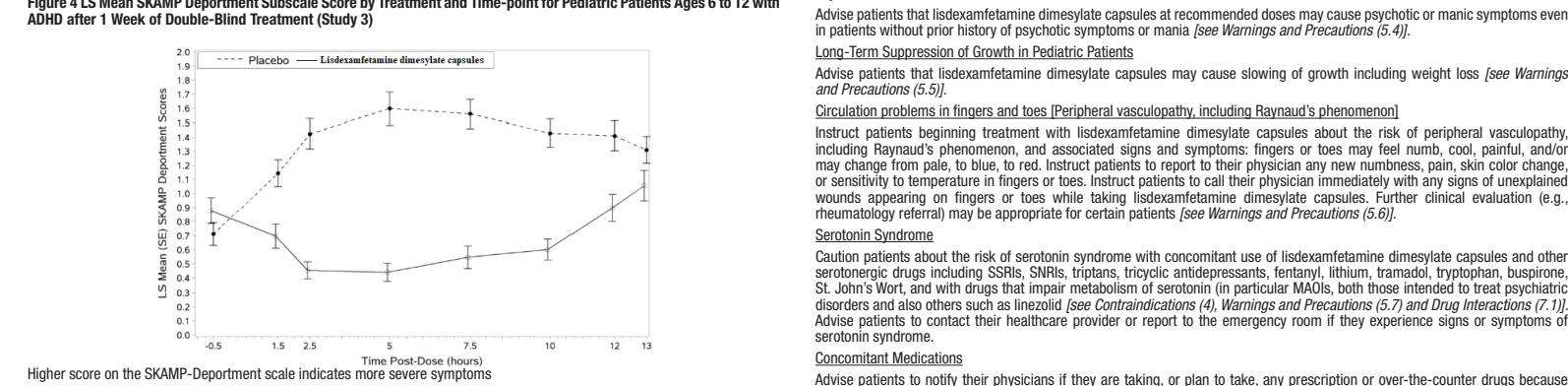


Figure 6: Mean (SE) PERMP Total Score by Treatment and Time-point for Adults Ages 18 to 55 with ADHD after 1 Week of Double-Blind Treatment (Study 8)
Higher score on the PERMP scale indicates less severe symptoms.

Figure 7: Mean (SE) PERMP Total Score by Treatment and Time-point for Adults Ages 18 to 55 with ADHD after 1 Week of Double-Blind Treatment (Study 9)
Higher score on the PERMP scale indicates less severe symptoms.

MEDICATION GUIDE

Lisdexamfetamine dimesylate (lis dex[®] am fet[®] a meen dye-mes[®]-i-late) Capsules, CII

What is the most important information I should know about lisdexamfetamine dimesylate capsules?

Lisdexamfetamine dimesylate capsules may cause serious side effects, including:

- **Abuse, misuse, and addiction.** Lisdexamfetamine dimesylate capsules has a high chance for abuse and misuse and may lead to substance use problems, including addiction. Misuse and abuse of lisdexamfetamine dimesylate capsules, other amphetamine containing medicines, and methylphenidate containing medicines, can lead to overdose and death. The risk of overdose and death is increased with higher doses of lisdexamfetamine dimesylate capsules or when it is used in ways that are not approved, such as snorting or injection.
 - Your healthcare provider should check you or your child's risk for abuse, misuse, and addiction before starting treatment with lisdexamfetamine dimesylate capsules and will monitor you or your child during treatment.
 - Lisdexamfetamine dimesylate capsules may lead to physical dependence after prolonged use, even if taken as directed by your healthcare provider.
 - Do not give lisdexamfetamine dimesylate capsules to anyone else. See **"What are lisdexamfetamine dimesylate capsules?"** for more information.
 - Keep lisdexamfetamine dimesylate capsules in a safe place and properly dispose of any unused medicine. See **"How should I store lisdexamfetamine dimesylate capsules?"** for more information.
 - Tell your healthcare provider if you or your child have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
- **Risks for people with serious heart disease.** Sudden death has happened in people who have heart defects or other serious heart disease. Your healthcare provider should check you or your child carefully for heart problems before starting treatment with lisdexamfetamine dimesylate capsules. Tell your healthcare provider if you or your child have any heart problems, heart disease, or heart defects.
Call your healthcare provider right away or go to the nearest hospital emergency room 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 lisdexamfetamine dimesylate capsules.
- **Increased blood pressure and heart rate.** Your healthcare provider should check you or your child's blood pressure and heart rate regularly during treatment with lisdexamfetamine dimesylate capsules.
- **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 healthcare provider about any mental problems you or your child have or about a family history of suicide, bipolar illness, or depression.

Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems during treatment with lisdexamfetamine dimesylate capsules, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

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

Call your healthcare provider right away if you or your child have any new or worsening mental symptoms or problems during treatment with lisdexamfetamine dimesylate capsules, especially hearing voices, seeing or believing things that are not real, or new manic symptoms.

What are lisdexamfetamine dimesylate capsules?

Lisdexamfetamine dimesylate capsules are a central nervous system (CNS) stimulant prescription medicine used for the treatment of:

- Attention Deficit Hyperactivity Disorder (ADHD) in adults and children 6 years of age and older. Lisdexamfetamine dimesylate capsules may help increase attention and decrease impulsiveness and hyperactivity in people with ADHD.
- Moderate to severe binge eating disorder (BED) in adults. Lisdexamfetamine dimesylate capsules may help reduce the number of binge eating days in people with BED.

Lisdexamfetamine dimesylate capsules are not recommended for use in children under 6 years of age with ADHD.

Lisdexamfetamine dimesylate capsules are not for weight loss. It is not known if lisdexamfetamine dimesylate capsules are safe and effective for the treatment of obesity.

It is not known if lisdexamfetamine dimesylate capsules are safe and effective for use in children with BED.

Lisdexamfetamine dimesylate capsules are 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 lisdexamfetamine dimesylate capsules in a safe place to protect it from theft. Never give your lisdexamfetamine dimesylate capsules to anyone else because it may cause death or harm them. Selling or giving away lisdexamfetamine dimesylate capsules may harm others and is against the law.

Who should not take lisdexamfetamine dimesylate capsules?

- Do not take lisdexamfetamine dimesylate capsules if you or your child are:
 - allergic to amphetamine products or any of the ingredients in lisdexamfetamine dimesylate capsules. See the end of this Medication Guide for a complete list of ingredients in lisdexamfetamine dimesylate capsules.
 - taking, or have stopped taking in the last 14 days, a medicine called a Monoamine Oxidase Inhibitor (MAOI), including the antibiotic linezolid or intravenous methylene blue.

Before taking lisdexamfetamine dimesylate capsules, tell your healthcare provider about all medical conditions, including if you or your child:

- have heart problems, heart disease, heart defects, or high blood pressure, or have a family history of sudden death or heart problems
- have mental problems including psychosis, mania, bipolar illness, or depression or have a family history of suicide, bipolar illness, or depression
- have circulation problems in fingers and toes
- have kidney problems
- have or had repeated movements or sounds (tics) or Tourette's syndrome, or have a family history of tics or Tourette's syndrome
- are pregnant or plan to become pregnant. Lisdexamfetamine dimesylate may harm the unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with lisdexamfetamine dimesylate.
- There is a pregnancy registry for females who are exposed to lisdexamfetamine dimesylate during pregnancy. The purpose of the registry is to collect information about the health of females exposed to lisdexamfetamine dimesylate and their baby. If you or your child becomes pregnant during treatment with lisdexamfetamine dimesylate, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychostimulants at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/clickable-and-research-programs/pregnancyregistry/adhd-medications/>.

Breastfeeding or plan to breastfeed. Lisdexamfetamine dimesylate passes into breast milk. You should not breastfeed during treatment with lisdexamfetamine dimesylate. Talk to your healthcare provider about the best way to feed the baby during treatment with lisdexamfetamine dimesylate.

Tell your healthcare provider about all the medicines that you or your child take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Lisdexamfetamine dimesylate capsules can affect the way other medicines work, and other medicines may affect how lisdexamfetamine dimesylate capsules work. Taking lisdexamfetamine dimesylate capsules with other medicines can cause serious side effects. Sometimes the doses of other medicines will need to be changed during treatment with lisdexamfetamine dimesylate capsules.

Especially tell your healthcare provider if you or your child take:

- selective serotonin reuptake inhibitors (SSRIs)
- serotonin norepinephrine reuptake inhibitors (SNRIs)
- medicines used to treat migraine headaches called triptans
- lithium
- tramadol
- buspirone
- St. John's Wort

Keep a list of all medicines to show your healthcare provider and pharmacist when you get a new medicine. Your healthcare provider will decide if lisdexamfetamine dimesylate capsules can be taken with other medicines.

Do not start any new medicine during treatment with lisdexamfetamine dimesylate capsules without talking to your healthcare provider first. Your healthcare provider may tell you to stop taking lisdexamfetamine dimesylate capsules for a short time before you get certain imaging tests because lisdexamfetamine dimesylate capsules may impact the results of some tests.

How should lisdexamfetamine dimesylate capsules be taken?

- Take lisdexamfetamine dimesylate capsules exactly as prescribed by your healthcare provider.
- Your healthcare provider may change the dose if needed.
- Take lisdexamfetamine dimesylate capsules 1 time each day in the morning with or without food.
- Taking lisdexamfetamine dimesylate capsules in the afternoon may cause trouble sleeping.
- Lisdexamfetamine dimesylate comes in capsules.
Taking Lisdexamfetamine dimesylate capsules:
 - Swallow lisdexamfetamine dimesylate capsules whole.
 - If lisdexamfetamine dimesylate capsules cannot be swallowed whole, the capsule may be opened and the entire contents sprinkled onto yogurt, or poured into water or orange juice.
 - Using a spoon, break apart any powder that is stuck together. Stir the lisdexamfetamine dimesylate capsules powder and yogurt, water, or orange juice until they are completely mixed together.
 - Swallow all the yogurt, water, or orange juice mixture right away. Do not store the yogurt, water, or orange juice mixture.
 - It is normal to see a filmy coating on the inside of your glass or container after you eat or drink all the lisdexamfetamine dimesylate capsules mixture.

If you or your child take too much lisdexamfetamine dimesylate capsules, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of lisdexamfetamine dimesylate capsules?

Lisdexamfetamine dimesylate capsules may cause serious side effects, including:

- See **"What is the most important information I should know about lisdexamfetamine dimesylate capsules?"**
- **Slowing of growth (height and weight) in children.** Children should have their height and weight checked often during treatment with lisdexamfetamine dimesylate capsules. Lisdexamfetamine dimesylate capsules treatment may be stopped if your child is not growing or gaining weight as expected.
- **Circulation problems in fingers and toes (peripheral vasculopathy, including Raynaud's phenomenon).** Signs and symptoms may include:
 - fingers or toes may feel numb, cool, painful
 - fingers or toes may change color from pale, to blue, to red

Tell your healthcare provider if you or your child have numbness, pain, skin color change, or sensitivity to temperature in your fingers or toes.

Call your healthcare provider right away if you or your child have any signs of unexplained wounds appearing on fingers or toes during treatment with lisdexamfetamine dimesylate capsules.

Serotonin syndrome. A potentially life-threatening problem called serotonin syndrome may happen when lisdexamfetamine dimesylate capsules is taken with certain other medicines. Stop taking lisdexamfetamine dimesylate capsules and call your healthcare provider or go to the nearest hospital emergency room 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

New or worsening tics or worsening Tourette's syndrome. Tell your healthcare provider if you or your child get any new or worsening tics or worsening Tourette's syndrome during treatment with lisdexamfetamine dimesylate capsules.

The most common side effects of lisdexamfetamine dimesylate capsules in children 6 to 17 years old and adults with ADHD include:

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

These are not all the possible side effects of lisdexamfetamine dimesylate capsules. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store lisdexamfetamine dimesylate capsules?

- Store lisdexamfetamine dimesylate capsules in a safe place (like a locked cabinet) at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the container tightly closed and protect lisdexamfetamine dimesylate capsules from light.
- Dispose of remaining, unused, or expired lisdexamfetamine dimesylate capsules by a medicine take-back program at a U.S. Drug Enforcement Administration (DEA) authorized collection site. If no take-back program or DEA authorized collector is available, mix lisdexamfetamine dimesylate capsules with an undesirable, nontoxic substance such as dirt, cat litter, or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw away lisdexamfetamine dimesylate capsules in the household trash. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

Keep lisdexamfetamine dimesylate capsules and all medicines out of the reach of children.

General information about the safe and effective use of lisdexamfetamine dimesylate capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use lisdexamfetamine dimesylate for a condition for which it was not prescribed. Do not give lisdexamfetamine dimesylate to other people, even if they have the same symptoms that you have. It may harm them and it is against the law. You can ask your pharmacist or healthcare provider for information about lisdexamfetamine dimesylate that is written for health professionals.

What are the ingredients in lisdexamfetamine dimesylate capsules?

Active ingredient: lisdexamfetamine dimesylate
Inactive Ingredients: Microcrystalline cellulose, croscarmellose sodium, magnesium stearate, gelatin, titanium dioxide and sodium lauryl sulfate. The ink ingredients common for all strengths are shellac, propylene glycol, strong ammonia solution, black iron oxide and potassium hydroxide.

Each strength capsule also contains colorant ingredients in the capsule shell as follows:

- 10 mg: FD&C Red No. 3
- 20 mg: Iron Oxide Yellow
- 30 mg: FD&C Red No. 3 and FD&C Yellow No. 6
- 40 mg: FD&C Red No. 3 and FD&C Blue No. 1
- 50 mg: FD&C Red No. 3 and FD&C Blue No. 1
- 60 mg: FD&C Blue No. 1 and D&C Red 28

For more information, call Camber Pharmaceuticals, Inc., at 1-866-495-8330.

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