**Zenzedi® (dextroamphetamine sulfate, USP)**

**ACUTE ADVERSE REACTIONS**

- Adverse effects: includes vomiting of solid and diastolic blood pressures and weak bronchodilator and respiratory stimulant action.

- Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or behavior that is dangerous to the patient or others. The prior history of disease, the potential for this drug to cause death by suicide at usual dosages.

- The extent of bioavailability of the sustained-release capsule was similar compared to the clinical hyperactivity. Subjects. The extent of bioavailability of the sustained-release capsule was similar compared to the tablet and fasted state.

- Cmax was 23.5 ng/mL. The average plasma T½ was similar for both the tablet and sustained-release capsule was 23 hours. Fasting administration of one 15 mg sustained-release capsule, maximal changes alone would not be expected to have short-term consequences, all patients should

- Seizures should have a careful history (including assessment for a family history of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. In the presence of seizures, the drug should be discontinued.

- Agitated states.

- Assessing Cardiovascular Status in Patients Being Treated with Stimulant Medications

- children and adolescents with structural cardiac abnormalities or other serious heart problems. Although some serious heart defects alone carry an increased risk of sudden death, stimulant products generally should not be used in children or adolescents with known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to the symptomatic effects of a stimulant drug.

- Dextroamphetamine sulfate can be used to treat ADHD in patients with prior evidence of ADHD, and should be considered only in light of the complete history and evaluation of the patient. Medication Guide and should assist them in understanding its contents. Patients and caregivers should be provided with the latest complete text of the Medication Guide is reprinted at the end of this document.

- Attention Deficit Disorder with Hyperactivity: As an integral part of a total treatment program, dextroamphetamine sulfate may also include other measures (psychological, educational, and social) for a stabilizing effect in pediatric patients (ages 3 to 16 years) with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe Attention Deficit Hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with facility when these symptoms are only of relatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

- Pharyngitis, laryngitis, elevation of blood pressure. There have been isolated reports of cardiovasculopathy associated with chronic amphetamine use.

- Cardiovascular System

- Psychotic episodes at recommended doses (rare), overstimulation, restlessness, distress, insomnia, euphoria, dyskinesia, dizziness, tremor, headache, exacerbation of motor and phonic tics and Tourette’s syndrome.

- Gastrointestinal

- Dryness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances. Anorexia and weight loss may occur as undesirable effects. Allergic, Urticaria, Endocrine

- Importantly, changes in libido, frequent or prolonged erections.

- Drug Abuse and Dependence

- Central Nervous System

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Amphetamines should be administered at the lowest effective dosage and dosage should be individually adjusted. Late evening doses should be avoided because of the resulting insomnia.

Nasal congestion in pediatric patients under 12 years of age; however, when it does, decongestant/acetaminophen tablets may be used. The suggested initial dose for patients aged 6 to 12 is 5 mg daily; daily dose may be raised in increments of 0.5 mg at weekly intervals until optimal response is obtained. In patients 12 years of age and older, start with 10 mg daily; daily dosage may be raised in increments of 10 mg at weekly intervals until an optimal response is obtained. If bothersome adverse reactions appear (e.g., insomnia or anxiety), dosage should be reduced. Give first dose on awakening; additional doses (1 or 2) at intervals of 4 to 6 hours.

Attention Deficit Hyperactivity Disorder: Not recommended for pediatric patients under 3 years of age.

In pediatric patients 3 to 5 years of age, start with 2.5 mg daily; daily dosage may be raised in increments of 0.5 mg at weekly intervals until optimal response is obtained.

In pediatric patients 6 years of age and older, start with 5 mg once or twice daily; daily dosage may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be necessary to exceed a total of 40 mg per day. Give first dose on awakening; additional doses (1 or 2) at intervals of 4 to 6 hours.

Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy.

HOW SUPPLIED
Zenzedi (dextroamphetamine sulfate tablets, USP) is supplied as follows:

- 2.5 mg: White, square tablet, debossed “2.5” on one side and “MA” on the other side in bottles of 100 tablets, NDC 24338-851-10.
- 7.5 mg: Light green, triangular tablet, debossed “7.5” on one side and “MA” on the other side in bottles of 100 tablets, NDC 24338-852-10.
- 10 mg: Peach, round tablet, double scored on one side and debossed “10” over “MA” on the other side in bottles of 100 tablets, NDC 24338-853-10.
- 15 mg: Light blue, hexagon tablet, debossed “30” on one side and “MA” on the other side in bottles of 100 tablets, NDC 24338-855-10.
- 30 mg: Light yellow, hexagon tablet, debossed “30” on one side and “MA” on the other side in bottles of 100 tablets, NDC 24338-856-10.

Dispense in well-closed containers as defined in the USP.

Store at 20° to 25°C (68°F to 77°F). Excursions permitted 15° to 30°C (59°F to 86°F). [See USP Controlled Room Temperature]

DEA Order Form Required.

Pharmacists: Medication Guide to be dispensed to Patients.

Manufactured for:
Arbor Pharmaceuticals, LLC
Atlanta, GA 30328

MEDICATION GUIDE

Zenzedi® (dextroamphetamine sulfate tablets, USP) C

Read the Medication Guide that comes with Zenzedi before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child’s treatment with Zenzedi.

Zenzedi is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Zenzedi in a safe place to prevent misuse and abuse. Selling or giving away Zenzedi may harm others, and is against the law.

Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines or street drugs.

Who should not take Zenzedi?

Zenzedi should not be taken if you or your child:

- Have heart disease or hardening of the arteries
- Have moderate to severe high blood pressure
- Have hypothyroidism
- Have an eye problem called glaucoma
- Are very anxious, tense, or agitated
- Have a history of drug abuse
- Are taking or have taken within the past 14 days an antidepressant medicine called a monoamine oxidase inhibitor or MAOI.
- Is sensitive to, allergic to, or had a reaction to other stimulant medicines

Zenzedi is not recommended for use in children less than 5 years old.

Zenzedi may not be right for you or your child. Before starting Zenzedi tell your or your child’s doctor about all health conditions (or a family history of) including:

- Heart problems, heart defects, high blood pressure
- Mental problems including psychosis, mania, bipolar illness, or depression
- Tics or Tourette’s syndrome
- Thyroid problems
- Seizures
- You or your child had an abnormal brain wave test (EEG)

Tell your doctor if you or your child is pregnant, planning to become pregnant, or breastfeeding.

Can Zenzedi be taken with other medicines?

Tell your doctor about all of the medicines that you or your child takes including prescription and nonprescription medicines, vitamins, and herbal supplements. Zenzedi and some medicines may interact with each other and cause serious side effects. Sometimes the doses of other medicines will need to be adjusted while taking Zenzedi.

Your doctor will decide whether Zenzedi can be taken with other medicines.

Especially tell your doctor or your child’s doctor:

- Antidepressant medicines including MAOIs
- Blood pressure medicines
- Antacids
- Seizure medicines

Know the medicines that you or your child takes. Keep a list of your medicines with you to show your doctor and pharmacist.

Do not start any new medicine while taking Zenzedi without talking to your doctor first.

How should Zenzedi be taken?

- Take Zenzedi exactly as prescribed. Your doctor may adjust the dose as long as it is right for you or your child.
- Zenzedi is usually taken two or three times a day. The first dose is usually taken in the morning. One or two more doses may be taken during the day. 4 to 6 hours apart.

From time to time, your doctor may stop Zenzedi treatment for a while to check ADHD symptoms.
- Your doctor may do regular checks of the blood, heart, and blood pressure while taking Zenzedi. Children should have their height and weight checked often while taking Zenzedi. Treatment may be stopped if a problem is found during these check-ups.
- If you or your child takes too much Zenzedi or overdoes, call your doctor or poison control center right away, or get emergency treatment.

What are possible side effects of Zenzedi?

See “What is the most important information I should know about Zenzedi?” for information on reported heart and mental problems.

Other serious side effects include:

- Slowing of growth (height and weight) in children
- Seizures, mainly in patients with a history of seizures
- Eye changes or blurred vision

Common side effects include:

- Fast heart beat
- Tremors
- Trouble sleeping
- Stomach upset
- Dry mouth
- Decreased appetite
- Headache
- Dizziness
- Weight loss

Zenzedi may affect your or your child’s ability to drive or do other dangerous activities.

Talk to your doctor if you or your child has side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Call your doctor for more medical advice about side effects. You may report side effects to Arbor Pharmaceuticals, LLC, Medical Information at 1-866-516-4950 or FDA at 1-800-FDA-1088.

How should I store Zenzedi?

- Store Zenzedi in a safe place at room temperature, 20° to 25°C (68°F to 77°F).
- Keep Zenzedi and all medicines out of the reach of children.

General information about Zenzedi

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Zenzedi for a condition for which it was not prescribed. Do not give Zenzedi to other people, even if they have the same condition. It may harm them and it is against the law.

This Medication Guide summarizes the most important information about Zenzedi. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Zenzedi that was written for healthcare professionals. For more information about Zenzedi you may also contact Arbor Pharmaceuticals LLC at 1-866-516-4950.

What are the ingredients in Zenzedi?

Active Ingredient: dextroamphetamine sulfate

Inactive Ingredients: colloidal silicon dioxide, crospovidone, microcrystalline cellulose and stearic acid. The 5 mg tablets contain D&C Red #7 and FD&C Yellow #6. The 7.5 mg tablets contain FD&C Blue #1 and D&C Yellow #10. The 10 mg tablets contain FD&C Red #40, FD&C Yellow #6 and FD&C Blue #2. The 15 mg tablets contain FD&C Blue #1, FD&C Blue #2, and FD&C Red #40. The 20 mg tablets contain FD&C Blue #1 and D&C Red #20. The 30 mg tablets contain D&C Yellow #10.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by Mckint Inc. Atlanta, GA 30318

For Arbor Pharmaceuticals LLC, Atlanta, GA 30328.

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