RELEXXII INDICATION & IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

INDICATION

RELEXXII is a central nervous system (CNS) stimulant indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in adults (up to the age of 65 years) and pediatric patients 6 years of age and older.

WARNING: ABUSE, MISUSE, AND ADDICTION

See full prescribing information for complete boxed warning.

RELEXXII 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 RELEXXII, can result in overdose and death.

- Before prescribing RELEXXII, 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.

- RELEXXII is contraindicated in patients with known hypersensitivity to methylphenidate or other components of RELEXXII.
- RELEXXII is contraindicated in patients with concurrent treatment of monoamine oxidase inhibitor (MAOI) or using MAOI within the preceding 14 days.
- Risks to Patients with Serious Cardiac Disease: Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or serious cardiac disease.
- Increased Blood Pressure and Heart Rate: Monitor blood pressure and pulse. Monitor all RELEXXII-treated patients for hypertension and tachycardia.
- Psychiatric Adverse Reactions: Prior to initiating RELEXXII, screen patients for risk factors for developing a manic episode. If new psychotic or manic symptoms occur, consider discontinuing RELEXXII.
- Priapism: If abnormally sustained or frequent and painful erections occur, patients should seek immediate medical attention.
- Peripheral Vasculopathy, including Raynaud's Phenomenon: Careful observation for digital changes is necessary during RELEXXII treatment. Further clinical evaluation (e.g., rheumatology referral) may be appropriate for patients who develop signs or symptoms of peripheral vasculopathy.
- Long-Term Suppression of Growth in Pediatric Patients: Closely monitor growth (height and weight) in pediatric patients. Pediatric patients not growing or gaining weight as expected may need to have their treatment interrupted.
- Gastrointestinal Obstruction: Avoid use with preexisting GI narrowing.
- Acute Angle Closure Glaucoma: RELEXXII treated patients considered at risk for acute angle closure glaucoma (e.g.,patients with significant hyperopia) should be evaluated by an ophthalmologist.
- Increased Intraocular Pressure (IOP) and Glaucoma: Prescribe RELEXXII to patients with open-angle glaucoma or abnormally increased IOP only if the benefit of treatment is considered to outweigh the risk. Closely monitor patients with a history of increased IOP or open angle glaucoma.
- Motor and Verbal Tics, and Worsening of Tourette's Syndrome: Before initiating RELEXXII, 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.

DRUG INTERACTIONS

- Concomitant use of Monoamine oxidase Inhibitor's (MAOIs) and CNS stimulants can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure. Do not administer RELEXXII concomitantly with MAOIs or within 14 days after discontinuing MAOI treatment.
- RELEXXII may decrease the effectiveness of drugs used to treat hypertension. Monitor blood pressure and adjust the dosage of the antihypertensive drug as needed.
- Concomitant use of halogenated anesthetics and RELEXXII may increase the risk of sudden blood pressure and heart rate increase during surgery. Avoid use of RELEXXII in patients being treated with anesthetics on the day of surgery.
- Combined use of methylphenidate with risperidone when there is a change in dosage of either or both medications, may increase the risk of extrapyramidal symptoms (EPS). Monitor patients on RELEXXII for signs of EPS with concomitant use of risperidone with associated changes in dosage.

You may report side effects to Vertical Pharmaceuticals, LLC at 1-800-444-5164 or to the FDA at 1-800-FDA-1088.

For Full Prescribing Information, including Boxed Warning, visit relexxii.com/pi or scan here

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