Precautions and Warnings: Refer to SPC for details and recommendations: For oral use. Take once daily in the morning. The tablet may be swallowed whole with liquids and must not be chewed, broken, divided, or crushed. It may be administered with or without food. Pre-treatment screening: Conduct a baseline evaluation of a patient's cardiovascular status including blood pressure and heart rate prior to prescribing. A comprehensive history should document concomitant medications, past and present co-morbid medical and psychiatric disorders, and history of sudden cardiac events. Prolonged-release measures alone are not sufficient. Treatment must be under the supervision of a specialist and evaluation of the patient. Diagnosis cannot be made solely on the presence of one or more symptoms. Xaggitin XL treatment is not indicated in all children with ADHD and the decision to use the medicinal product must be based on a thorough assessment of the severity and duration of the condition (see above). Patients with additional risk factors should be assessed at every 3-6 months.

Cerebrovascular disorders

Serious cardiac disorders

Elderly or children under 6 years:

Patients Currently Using Methylphenidate:

Dosage and Administration:

Addison's disease: The use of methylphenidate in children with Addison's disease and those who have experienced an adrenal crisis is not recommended.

Drug screening:

For the woman.

Use with dopaminergic (agonists and antagonists including antipsychotics) medicinal products: Anti-hypertensive medicinal products may decrease the effectiveness of anti-hypertensives. Use with medicinal products that elevate blood pressure: Sudden death has been reported in association with the use of methylphenidate in children with pre-existing psychiatric disorders. Methylphenidate should be used with caution in patients with known drug or alcohol dependency because of a potential for abuse. Prisopron: Patients who develop abdominal discomfort, which is not relieved by a diet modification, should be advised to discontinue methylphenidate. Use with serotonergic medicinal products: Serotonin syndrome has been reported following co-administration with serotonergic medicinal products. If concomitant use is warranted, prompt recognition of serotonin syndrome is important: these may include mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. Discontinue methylphenidate as soon as possible if serotonin syndrome is suspected. Withdrawal: Careful supervision is required during withdrawal. Long-term use of methylphenidate may be associated with a risk of paradoxical agitation (e.g. irritability, aggression, insomnia, nervousness and headache).

Use in adults, elderly or children under 6 years of age: See above. Use with halogenated anesthetics: Risk of sudden blood pressure increase during surgery. If surgery is planned, methylphenidate treatment should not be used on the day of surgery. Use with centrally acting alpha-2 agonists (e.g. clonidine): Long-term safety of concomitant administration of methylphenidate has not been evaluated. Use with dopaminergic (agonists and antagonists including antipsychotics) medicinal products: Caution. Fertility, pregnancy and lactation: Fertility: No relevant effects observed. Pregnancy: Data from a cohort study of in total approximately 3,400 pregnancies exposed in the first trimester do not suggest an increased risk of overall birth defects. There was a small increased occurrence of cardiac malformations corresponding to 3 additional infants born with congenital cardiac malformations for every 1,000 women who receive methylphenidate during the first trimester of pregnancy, compared with non-exposed pregnancies.

Drug interactions:

Preparations and warnings: Refer to SPC for details and recommendations: Long-term use (more than 12 months) in children and adolescents: Methylphenidate treatment is usually discontinued during or after puberty. If prescribed for extended periods (over 12 months), the long-term usefulness of treatment with methylphenidate should be periodically re-evaluated with trial periods off medication to assess the patient's functioning without pharmacotherapy. It is recommended that methylphenidate be de-challenged at least once yearly to assess the child's condition. Dose reduction and discontinuation: Treatment must be stopped if the symptoms do not improve after appropriate dosage adjustment over a one-month period. If paradoxical aggravation of symptoms is noted, the medication should be discontinued. Adults: In adolescents, whose symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood. Initiation of treatment with Xaggitin XL in adults is not appropriate.

Contraindications:

Hypersensitivity to the active substance or to any of the excipients, glaucoma, pheochromocytoma, during treatment with non-selective, irreversible monoamine oxidase (MAO) inhibitors, or within a minimum of 14 days of discontinuing those medicinal products, hyperthyroidism or thyrotoxicosis, diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder, diagnosis or history of severe and epidemic (Type I) Bipolar (affective) Disorder that is not well-controlled, pre-existing cardiovascular disorders including severe heart disease/hypertension, heart failure/heart valve disease, symptomatic, significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening arrhythmias and channelopathies (in caused by the dysfunction of ion channels), pre-existing cerebrovascular disorders, cerebral aneurysm, vascular abnormalities including varicellal or stroke. Precautions and Warnings: Refer to SPC for details and recommendations: Long-term use (more than 12 months) in children and adolescents: Careful ongoing monitoring for cardiovascular status, growth, appetite, development of de novo or worsening of pre-existing psychiatric disorders. Psychiatric disorders to monitor for include (but are not limited to) motor or vocal tics, aggressive or hostile behaviour, agitation, anxiety, depression, psychosis, mania, delusions, irritability, lack of spontaneity, withdrawal and excessive perseveration. The use of methylphenidate for over 12 months in children and adolescents with ADHD should be periodically re-evaluated. Recommended that methylphenidate is de-challenged at least once yearly to assess the child's condition. Dose reduction and discontinuation: Treatment must be stopped if the symptoms do not improve after appropriate dosage adjustment over a one-month period. If paradoxical aggravation of symptoms is noted, the medication should be discontinued. Adults: In adolescents, whose symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood. Initiation of treatment with Xaggitin XL in adults is not appropriate.

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