NOVARTIS

אפריל 2024

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

הנדון:
Ritalin LA 10, 20, 30, 40 mg, modified release capsules
Ritalin 10 mg tablets

אנו מבקשים להודיע על עדכונים נוספים בעלון לרופא של תכשירי ריטלין.

התכשיר **Ritalin LA modified release capsules** רשום בישראל להתוויה הבאה:
Attention Deficit Hyperactivity Disorder (ADHD)

התכשיר **Ritalin 10 mg tablets** רשום בישראל להתוויות הבאות:
Attention Deficit Hyperactivity Disorder (ADHD)
Narcolepsy

המרכיב הפעיל: Methylphenidate Hydrochloride.

להלן פירוט השינויים המהותיים בלבד (ללא שינויי נוסח, עריכה, אדמיניסטרציה וכו'):

WARNING: ABUSE, MISUSE, AND ADDICTION
Ritalin 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 Ritalin, can result in overdose and death (see section 4.9 Overdose), and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.
Before prescribing Ritalin, 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 Ritalin treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction (see section 4.4 Special warnings and precautions for use).

4.4 Special warnings and precautions for use

Drug abuse, misuse, addiction, and dependence

Chronic abuse of Ritalin can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes may occur, especially with parenteral abuse. Clinical data indicate that children given Ritalin are not more likely to abuse drugs as adolescents or adults.

Caution is called for in emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because they may increase the dosage on their own initiative.

Abuse, misuse, and addiction

Before prescribing Ritalin, 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 Ritalin in a safe place, preferably locked, and instruct patients to not give Ritalin to anyone else. Throughout Ritalin treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction.

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Ritalin has a high potential for abuse and misuse which can lead to the development of a substance use disorder, including addiction. Ritalin 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. 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.

Misuse and abuse of methylphenidate hydrochloride may cause increased heart rate, respiratory rate, or blood pressure; 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 observed with CNS stimulants abuse and/or misuse. Misuse and abuse of CNS stimulants, including Ritalin, can result in overdose and death (see 4.9 Overdosage), and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.

Dependence

Physical Dependence

Ritalin may produce physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug.

Withdrawal signs and symptoms after abrupt discontinuation or dose reduction following prolonged use of CNS stimulants including Ritalin include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.

Tolerance

Ritalin may produce tolerance. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).

Cardiovascular

Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems:

… Stimulant products generally should not be used in patients with known structural cardiac abnormalities, ~~cardiomyopathy, serious heart rhythm abnormalities~~ or other serious cardiac disorders that may increase the risk of sudden death due to sympathomimetic effects of a stimulant drug.

~~**Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications**~~

~~Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram).~~

~~Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation.~~

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Psychiatric

~~**Bipolar Illness**~~

~~Particular care should be taken in using stimulants to treat ADHD in patients with comorbid bipolar disorder because of concern for possible induction of a mixed/ manic episode in such patients. Prior to initiating treatment with a stimulant, patients with comorbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression.~~

Induction of a Manic Episode in Patients with Bipolar Disorder

CNS stimulants may induce a manic or mixed mood episode in patients. Prior to initiating Ritalin 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, or depression).

~~**Emergence of**~~ **New Psychotic or Manic Symptoms**

~~Treatment emergent~~ CNS stimulants, at the recommended dosage, may cause psychotic or manic symptoms~~,~~ (e.g., hallucinations, delusional thinking, or mania) in patients ~~children and adolescents without a prior history of psychotic illness or mania can be caused by stimulants at usual doses~~.

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 treatment ~~consideration should be given to a possible causal role of the stimulant, and discontinuation of treatment may be appropriate~~.

~~In a pooled analysis of multiple short-term, placebo-controlled studies, such symptoms occurred in about 0.1% (4 patients with events out of 3,482 exposed to methylphenidate or amphetamine for several weeks at usual doses) of stimulant-treated patients compared to 0 in placebo-treated patients.~~

~~**Psychotic symptoms:**~~

~~Psychotic symptoms, including visual and tactile hallucinations or mania have been reported in patients administered usual prescribed doses of stimulant products, including Ritalin (see section 4.8 Undesirable effects). Physicians should consider treatment discontinuation.~~

העלון לרופא נשלח למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי פניה לבעל הרישום.

בברכה,
נוברטיס ישראל בע"מ

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