Osmolex ER™ (amantadine) Extended-release Tablets

WARNINGS AND PRECAUTIONS, continued

Withdrawal-Emergent Hyperpyrexia and Confusion: Abrupt discontinuation of OSMOLEX ER may cause an increase in the symptoms of Parkinson's disease or cause delirium, agitation, delusions, hallucinations, paranoid reaction, stupor, anxiety, depression, or slurred speech. It is recommended that patients avoid sudden discontinuation of OSMOLEX ER.

Impulse Control/Compulsive Behaviors: Patients can experience increased sexual urges, and intense urges to gamble, spend money, binge eat, and/or other intense urges, and the inability to control these urges while taking one or more medications that increase central dopaminergic tone, including OSMOLEX ER. It is important for prescribers to specifically ask patients or their caregivers about the development of new or increased urges while being treated with OSMOLEX ER. Consider dose reduction or stopping the medication if a patient develops such urges while taking OSMOLEX ER.

ADVERSE REACTIONS

The most common adverse reactions reported in ≥5% of patients at the recommended dosage of immediate-release amantadine were nausea, dizziness/lightheadedness, and insomnia.

DRUG INTERACTIONS

Other Anticholinergic Drugs: The dose of anticholinergic drugs or of OSMOLEX ER should be reduced if atropine-like effects appear when these drugs are used concurrently.

Please see additional Important Safety Information on reverse side and accompanying Full Prescribing Information, in pocket.

IMPORTANT SAFETY INFORMATION, continued

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DRUG INTERACTIONS, continued

Drugs Affecting Urinary pH: The pH of urine has been reported to influence the excretion rate of amantadine. Alterations in urine pH towards the alkaline condition may lead to an accumulation of the drug with a possible increase in adverse reactions. Monitor for efficacy or adverse reactions under conditions that alter the urine pH to more acidic or alkaline, respectively.

Live Attenuated Influenza Vaccines: Amantadine may interfere with the efficacy of live attenuated influenza vaccines. Therefore, live vaccines are not recommended during treatment with OSMOLEX ER. Inactivated influenza vaccines may be used as appropriate.

Alcohol: Concomitant use with alcohol is not recommended, as it may increase the potential for central nervous system effects such as somnolence, dizziness, confusion, lightheadedness, and orthostatic hypotension.

For more information, visit OSMOLEX.com

Please see additional Important Safety Information inside and accompanying Full Prescribing Information, in pocket.

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VERTICAL PHARMACEUTICALS, LLC

OSMOLEX ER™ (amantadine) extended-release tablets

Quick Reference Dosing Instructions

The recommended initial dose of OSMOLEX ER is 129 mg taken orally once a day in the morning. The dosage may be increased in weekly intervals to a maximum daily dose of 322 mg (administered as a 129 mg and a 193 mg tablet).

Osmolex ER™ (amantadine) Extended-release Tablets	Amantadine HCl Equivalent
129 mg	160 mg
193 mg	240 mg
258 mg	320 mg
322 mg *(taken as 2 tablets - 129 mg + 193 mg)*	400 mg

NOTE: The USP Salt Policy (May 2013) requires the name and strength of the active ingredient in a drug product be expressed in terms of the active moiety rather than the salt strength equivalent.

INDICATION

OSMOLEX ER™ (amantadine) extended-release tablets is indicated for the treatment of Parkinson's disease and for the treatment of drug-induced extrapyramidal reactions in adult patients.

CONTRAINDICATION

OSMOLEX ER is contraindicated in patients with end-stage renal disease (i.e., creatinine clearance below 15 mL/min/1.73 m^2).

Please see additional Important Safety Information inside and accompanying Full Prescribing Information, in pocket.

IMPORTANT SAFETY INFORMATION, continued

WARNINGS AND PRECAUTIONS

Falling Asleep During Activities of Daily Living and Somnolence: Patients treated with amantadine have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes has resulted in accidents. Patients may not perceive warning signs, such as excessive drowsiness, or they may report feeling alert immediately prior to the event. Before initiating treatment with OSMOLEX ER, advise patients of the potential to develop drowsiness and specifically ask about factors that may increase the risk of somnolence with OSMOLEX ER, such as concomitant sedating medications, alcohol, or the presence of a sleep disorder. If a patient develops daytime sleepiness or episodes of falling asleep during activities that require full attention (eg, driving a motor vehicle, conversations, eating), OSMOLEX ER should ordinarily be discontinued. If a decision is made to continue OSMOLEX ER, advise patients not to drive and to avoid other potentially dangerous activities that might result in harm if they become somnolent.

Suicidality and Depression: Suicide, suicide attempts, and suicidal ideation have been reported in patients with and without prior history of psychiatric illness while treated with amantadine. Monitor patients for depression, including suicidal ideation or behavior. Prescribers should consider whether the benefits of treatment with OSMOLEX ER outweigh the risks in patients with a history of suicidality or depression.

Hallucinations/Psychotic Behavior: Patients with a major psychotic disorder should ordinarily not be treated with OSMOLEX ER due to the risk of exacerbating psychosis. Monitor patients for hallucinations throughout treatment but especially after initiation and after the dose of OSMOLEX ER is increased or decreased.

Dizziness and Orthostatic Hypotension: Patients should be monitored for these adverse reactions, especially after starting OSMOLEX ER or increasing the dose.