You're invited to a **LOCAL SPEAKER** PROGRAM

APTIOM® (eslicarbazepine acetate)

IS DESIGNED FOR FINE TUNING

Program Objectives

During this presentation, a distinguished clinical expert will present the clinical profile of APTIOM, indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Participants will have the opportunity to interact with the presenter in an informal group setting, and are encouraged to ask questions and share their experiences in the management of epilepsy.

This promotional, non-CME program is intended for US health care professionals involved in the treatment of patients 4 years of age and older with partial-onset seizures.

Featured Presenter

Jason Bisping, MD
Adult Epileptologist
Department of Neurology
Ohio Health Comprehensive Epilepsy Center
Columbus, OH

The speaker is a paid consultant of and is speaking on behalf of Sunovion Pharmaceuticals Inc.

Registration

To register for this Local Speaker Program:

LOG ON TO
www.APTIOMmeetings.com

— OR —

CALL
(877) 829-1266

When registering for this event, please be sure to enter the meeting registration code.

Meeting registration code: 207773

Event Details

Thursday, August 29, 2019

6:30 PM

The Capital Grille
25389 Cedar Rd
Lyndhurst, OH 44124
216-382-5093

Sunovion Representative:
Michael Toth
Michael.Toth@sunovion.com
440-552-4167

Attendees will have the option to accept the Sunovion-provided food and beverage service, opt out of all food and beverage, or purchase their own food and beverage.

IMPORTANT SAFETY INFORMATION

Indications and Usage

APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.

Important Safety Information for APTIOM

Contraindications: APTIOM is contraindicated in patients with a hypersensitivity to eslicarbazepine acetate or oxcarbazepine.

Please see additional Important Safety Information and accompanying Full Prescribing Information.

ONCE DAILY
Aptiom®
(eslicarbazepine acetate) tablets
200 mg • 400 mg • 600 mg • 800 mg

sunovion

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Important Safety Information for Aptiom® (eslicarbazepine acetate) (cont.)

Suicidal Behavior and Ideation: Antiepileptic drugs (AEDs), including APTIOM, increase the risk of suicidal thoughts or behavior. Anyone considering prescribing APTIOM or any other AED must balance this risk with the risk of untreated illness. Epilepsy and many other illnesses for which AEDs are prescribed are themselves associated with morbidity and mortality and an increased risk of suicidal thoughts and behavior. Patients treated with any AED for any indication should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Patients and caregivers should also be advised to be alert to these behavioral changes and to immediately report them to the health care provider.

Serious Dermatologic Reactions, including Stevens-Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in association with APTIOM use. Serious and sometimes fatal dermatologic reactions, including TEN and SJS, have also been reported in patients using oxcarbazepine or carbamazepine, which are chemically related to APTIOM. Should a patient develop a dermatologic reaction while using APTIOM, discontinue APTIOM use unless it is clearly not drug related.

Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), also known as **Multiorgan Hypersensitivity**, has been reported in patients taking APTIOM. DRESS typically, although not exclusively, presents with fever, rash, and/or lymphadenopathy, in association with other organ system involvement. If this reaction is suspected, treatment with APTIOM should be discontinued.

Anaphylactic Reactions and Angioedema: Rare cases of anaphylaxis and angioedema have been reported in patients taking APTIOM. Anaphylaxis and angioedema associated with laryngeal edema can be fatal. If a patient develops any of these reactions, the drug should be discontinued. Patients with a prior anaphylactic-type reaction after treatment with either oxcarbazepine or APTIOM should not be treated with APTIOM.

Hyponatremia: Clinically significant hyponatremia (sodium <125 mEq/L) and syndrome of inappropriate antidiuretic hormone secretion (SIADH) can develop in patients taking APTIOM. Measurement of serum sodium and chloride levels should be considered during maintenance treatment with APTIOM, particularly if the patient is receiving other medications known to decrease serum sodium levels. Depending on the severity of hyponatremia, the dose of APTIOM may need to be reduced or discontinued.

Neurological Adverse Reactions: APTIOM causes dose-dependent increases in the following reactions (dizziness, disturbance in gait and coordination, somnolence, fatigue, and visual changes). There was an increased risk of dizziness, disturbance in gait and coordination, and visual changes during the titration period (compared to maintenance treatment), and there may be an increased risk of these adverse reactions in patients 60 years of age and older compared to younger adults. APTIOM causes dose-dependent increases in cognitive dysfunction-related events in adults (memory impairment, disturbance in attention, amnesia, confusional state, aphasia, speech disorder, slowness of thought, disorientation, and psychomotor retardation). The incidences of dizziness and diplopia were greater with concomitant use of APTIOM and carbamazepine compared to the use of APTIOM without carbamazepine.

Prescribers should advise patients against engaging in hazardous activities requiring mental alertness, such as operating motor vehicles or dangerous machinery, until the effect of APTIOM is known.

Withdrawal of AEDs: As with all AEDs, APTIOM should be withdrawn gradually because of the risk of increased seizure frequency and status epilepticus, but if withdrawal is needed because of a serious adverse event, rapid discontinuation can be considered.

Drug Induced Liver Injury: Hepatic effects, ranging from mild to moderate elevations in transaminases (>3 times the upper limit of normal) to rare cases with concomitant elevations of total bilirubin (>2 times the upper limit of normal) have been reported with APTIOM use. Baseline evaluations of liver laboratory tests are recommended. APTIOM should be discontinued in patients with jaundice or other evidence of significant liver injury.

Abnormal Thyroid Function Tests: Dose-dependent decreases in serum T3 and T4 (free and total) values have been observed in patients taking APTIOM. These changes were not associated with other abnormal thyroid function tests suggesting hypothyroidism. Abnormal thyroid function tests should be clinically evaluated.

Hematologic Adverse Reactions: Rare cases of pancytopenia, agranulocytosis, and leukopenia have been reported during postmarketing use in patients treated with APTIOM. Discontinuation of APTIOM should be considered in patients who develop pancytopenia, agranulocytosis, or leukopenia.

Most Common Adverse Reactions: The most common adverse reactions in adult patients receiving APTIOM (≥4% and ≥2% greater than placebo) were dizziness, somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, and tremor. Adverse reactions in pediatric patients are similar to those seen in adult patients.

Safety and Efficacy in Patients <4 Years of Age: Safety and effectiveness in patients below 4 years of age have not been established.

Dosing Considerations

Some adverse reactions occur more frequently when patients take APTIOM adjunctively with carbamazepine. When APTIOM and carbamazepine are taken concomitantly, the dose of APTIOM or carbamazepine may need to be adjusted based on efficacy and tolerability. APTIOM should not be taken as an adjunctive therapy with oxcarbazepine. For patients taking other enzyme-inducing AEDs (i.e., phenobarbital, phenytoin, and primidone), higher doses of APTIOM may be needed.

A dose reduction is recommended in patients with moderate and severe renal impairment (i.e., creatinine clearance <50 mL/min).

Dose adjustments are not required in patients with mild to moderate hepatic impairment. Use of APTIOM in patients with severe hepatic impairment has not been studied, and use in these patients is not recommended.

Concomitant use of APTIOM and oral contraceptives containing ethinylestradiol and levonorgestrel is associated with lower plasma levels of these hormones. Patients should use additional or alternative non-hormonal birth control during APTIOM treatment and after discontinuation of APTIOM for one menstrual cycle, or until otherwise instructed.

Please see accompanying Full Prescribing Information.

Sunovion Pharmaceuticals Inc. is committed to the principles in the PhRMA Code on Interactions with Health Care Professionals. This code helps to ensure that the highest professional and ethical standards are being met in the pharmaceutical industry. As part of our commitment to the PhRMA code, please note that attendance at this program is limited to health care professionals, and inclusion of spouses or other guests is not permitted.

Sunovion complies with all state and federal aggregate spend reporting laws that require the company to publicly disclose remuneration of identified health care professionals to government agencies.

Attention: all New Jersey licensed Prescribers (Physicians, Podiatrists, Physician Assistant, Advanced Practice Nurse, Dentist, and Optometrist) MUST identify yourself to the Sunovion representative at the presentation. The meal associated with this event exceeds the $15 meal cap (breakfast/lunch) or $25 meal cap (dinner). You may still attend this event and either opt-out of the meal provided or pay out of pocket for the meal.

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