Aptiom® (eslicarbazepine) – Expanded indication, new warning

- On September 14, 2017, Sunovion announced the FDA approval of Aptiom (eslicarbazepine), for the treatment of partial-onset seizures in patients 4 years of age and older.
    - Previously, Aptiom was approved for the treatment of partial-onset seizures as monotherapy or adjunctive therapy in adult patients.
- Safety and effectiveness of Aptiom have been established in the age groups 4 to 17 years.
    - Use of Aptiom in these age groups is supported by evidence from adequate and well-controlled studies of Aptiom in adults with partial-onset seizures, pharmacokinetic data from adult and pediatric patients, and safety data from clinical studies in 393 pediatric patients 4 to 17 years of age.
- The recommended dosage of Aptiom in pediatric patients is based on body weight and is administered orally once daily. The dose may be increased in weekly intervals based on clinical response and tolerability, to the recommended maintenance dosage.

Body Weight	Initial and Maximum Titration Increment Dosage (mg/day)	Maintenance Dosage (mg/day)
11 – 21 kg	200	400 – 600
22 – 31 kg	300	500 – 800
32 – 38 kg	300	600 – 900
> 38 kg	400	800 - 1200

- Consult Aptiom's drug label for the recommended adult dosage.
- The *Warnings and Precautions* section was also updated with information regarding the risk of 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.