

## **FDA Drug Safety Warning: FDA Suspends Pediatric Sensipar® (Cinacalcet Hydrochloride) Clinical Trials After Report Of Death (26 Feb 2013)**

Pharmacy, Patient Safety, Endocrinology, and Pediatrics communities: Please share with pharmacists and providers at your MTFs and regions.

**ISSUE:** FDA has stopped all pediatric clinical trials of Sensipar® (cinacalcet hydrochloride) after the recent death of a 14-year-old patient in a trial. The FDA has not concluded whether or not Sensipar® had a role in the patient's death. This communication is intended to inform health care professionals that the FDA is evaluating the information and will communicate final conclusions and recommendations when their review is complete.

**BACKGROUND:** Sensipar® is a calcium-sensing receptor agonist indicated in adults for secondary hyperparathyroidism in patients with chronic kidney disease on dialysis, hypercalcemia in patients with parathyroid cancer and severe hypercalcemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy. FDA has approved Sensipar® for use in adults but not in children (less than 18 years of age), and the clinical trials were underway to determine if the drug is effective and can be used safely in children.

**SENSIPAR® USE IN THE DoD:** A Pharmacovigilance Center (PVC) analysis conducted in response to this FDA safety warning found 5 (five) children (age less than 18 years) filled prescriptions for Sensipar® in the 1<sup>st</sup> quarter of FY13 (October 1, 2012 thru January 31, 2013). All five were prescribed and received Sensipar® from network providers and network pharmacies. No MTF prescribing or dispensing of Sensipar® to children less than 18 years of age occurred in this time period.

### **RECOMMENDATIONS:**

- Patients should be monitored for the development of low serum calcium levels (hypocalcemia) since Sensipar® lowers calcium levels in the blood.
- The potential signs of low serum calcium levels include muscular problems such as muscle cramping, tetany, convulsions, paresthesias, and myalgias.
- If serum calcium levels decrease below the normal range, appropriate steps should be taken to increase calcium levels, such as by providing supplemental calcium, initiating or increasing the dose of a calcium-based phosphate binder, initiating or increasing the dose of vitamin D sterols, or temporarily withholding treatment with Sensipar®.
- Serum calcium levels should be measured within 1 week after initiation or dose adjustment of Sensipar®. Once a maintenance dose has been established, serum calcium should be measured monthly.

The entire FDA Drug Safety Communication is available at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm341255.htm>

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program at: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

**QUESTIONS OR ADDITIONAL INFORMATION:** Send requests for additional information regarding this alert or the analysis conducted by the Pharmacovigilance Center (PVC) to: [mark.s.maneval2.mil@mail.mil](mailto:mark.s.maneval2.mil@mail.mil)