



Sensipar® (cinacalcet) – New warning

- On May 15, 2017, the [FDA approved](#) an update to the *Warnings and Precautions* section of the [Sensipar \(cinacalcet\)](#) drug label, regarding upper gastrointestinal (GI) bleeding.
- Sensipar is indicated for the treatment of: secondary hyperparathyroidism (HPT) in adult patients with chronic kidney disease (CKD) on dialysis, hypercalcemia in adult patients with parathyroid carcinoma, and hypercalcemia in adult patients with primary HPT for whom parathyroidectomy would be indicated on the basis of serum calcium levels, but who are unable to undergo parathyroidectomy.
 - Sensipar is not indicated for use in adult patients with CKD who are not on dialysis because of an increased risk of hypocalcemia.
- Cases of GI bleeding, mostly upper GI bleeding, have occurred in patients using calcimimetics, including Sensipar, from postmarketing and clinical trial sources. The exact cause of GI bleeding in these patients is unknown.
 - Patients with risk factors for upper GI bleeding (such as known gastritis, esophagitis, ulcers or severe vomiting) may be at increased risk for GI bleeding when receiving Sensipar treatment.
 - Patients should be monitored for worsening of common GI adverse reactions of nausea and vomiting associated with Sensipar and for signs and symptoms of GI bleeding and ulcerations during Sensipar therapy.

Patients should be promptly evaluated and treated for any suspected GI bleeding.



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