

Sensipar® (cinacalcet) - New warning

- On May 23, 2017, the <u>FDA approved</u> an update to the Warnings and Precautions section of the <u>Sensipar (cinacalcet)</u> drug label regarding hypotension, worsening heart failure (HF) and/or arrhythmias.
- 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.
- In post marketing safety surveillance, isolated, idiosyncratic cases of hypotension, worsening HF, and/or arrhythmia have been reported in patients with impaired cardiac function, in which a causal relationship to Sensipar could not be completely excluded and which may be mediated by reductions in serum calcium levels.



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