



Zemplar® (paricalcitol) – Expanded Indications

- On October 18, 2016, the [FDA announced](#) the approval of AbbVie's [Zemplar \(paricalcitol\)](#) capsules for pediatric patients 10 years and older for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) stages 3 and 4 and CKD stage 5 in patients on hemodialysis or peritoneal dialysis.
 - Previously, Zemplar capsules were not indicated in pediatric patients.
- Zemplar is also available generically as capsules and an [injectable solution](#).
 - The injectable solution is indicated for the prevention and treatment of secondary hyperparathyroidism associated with CKD stage 5.
- The efficacy of Zemplar in patients 10-16 years of age was demonstrated in a clinical study of 36 patients with CKD stages 3 and 4. The primary efficacy endpoint was the proportion of patients achieving two consecutive $\geq 30\%$ reductions from baseline in iPTH levels.
 - A statistically significantly greater proportion of Zemplar patients achieved the primary endpoint vs. placebo (28% vs. 0%, respectively; $p < 0.05$).
- The recommended dose of Zemplar capsules in patients 10-16 years of age is as follows:
 - CKD stages 3 and 4: 1 mcg administered orally three times per week.
 - CKD stage 5: dose (mcg) = baseline iPTH (pg/mL) / 120. Administer orally three times per week.
 - The Zemplar dose should be individualized and titrated based on iPTH, serum calcium and phosphorus levels to maintain an iPTH level within target range.
 - Consult package label for recommended adult dosages.



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