

Auryxia[®] (ferric citrate) – New indication

- On November 7, 2017, <u>Keryx Biopharmaceuticals announced</u> the FDA approval of <u>Auryxia (ferric citrate)</u> for the treatment of iron deficiency anemia in adult patients with chronic kidney disease (CKD) not on dialysis.
 - Auryxia is also indicated for the control of serum phosphorus levels in adult patients with CKD on dialysis.
- In the U.S., one out of every seven adults has CKD. People with CKD often have anemia as a result
 of insufficient iron (called iron deficiency anemia) and don't produce enough hemoglobin (Hgb), the
 component of the red blood cell that carries oxygen throughout the body. Iron deficiency anemia
 can negatively impact a patient's quality of life and is associated with cardiovascular complications
 and increased mortality risk.
- The efficacy of Auryxia for the treatment of iron deficiency anemia in patients with CKD not on dialysis was demonstrated in a 24-week, placebo-controlled study of 232 patients. The main efficacy outcome was the proportion of subjects achieving an increase in Hgb of ≥ 1.0 g/dL.
 - An increase in Hgb of \geq 1.0 g/dL was achieved in 52% of the Auryxia-treated patients vs. 19% of the placebo patients (p < 0.001).
- The recommended starting dose of Auryxia for the treatment of iron deficiency anemia in patients with CKD not on dialysis is 1 tablet orally 3 times per day with meals. The dose may be titrated as needed to achieve and maintain Hgb at target levels, up to a maximum dose of 12 tablets daily.
 - Consult the Auryxia drug label for dosage recommendations for the control of phosphorus levels in adult patients with CKD on dialysis.



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