November 9, 2016

SUBJECT: Notification of Re-Supply of AURYXIA® (ferric citrate) tablets

Dear Healthcare Professional,

On August 1st of this year I had the unfortunate responsibility of informing you that Keryx would be unable to ensure continued supply of AURYXIA® (ferric citrate) tablets to patients due to an unexpected production issue at our contract manufacturing facility. At that time, I let you know that we were working to remedy the situation with the expectation of restoring supply in the fourth quarter of the year.

I’m pleased to announce today that FDA has approved our second manufacturer and supply of AURYXIA has been fully restored. Effective immediately, AURYXIA is once again available to patients at pharmacies.

At Keryx, we strive to be a trusted member of the renal treatment community and know that with that membership comes responsibility. Providing an uninterrupted supply of our medicine to patients is perhaps our greatest responsibility and for the past several months we fell short of that obligation. I want to take this opportunity to personally thank you for your patience and understanding during this situation and to assure you of Keryx’s commitment to do everything in our power to ensure that it never happens again. Keryx and its employees are anxious to begin earning back your trust and we look forward to working together to improve the lives of patients living with kidney disease.

Sincerely,

Greg Madison
Chief Executive Officer

INDICATION

AURYXIA® (ferric citrate) is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

IMPORTANT SAFETY INFORMATION

Contraindication

AURYXIA is contraindicated in patients with iron overload syndromes, e.g. hemochromatosis.
Warnings and Precautions

Iron Overload: Iron absorption from AURYXIA® (ferric citrate) may lead to excessive elevations in iron stores. Increases in serum ferritin and transferrin saturation (TSAT levels) were observed in clinical trials. Assess iron parameters, e.g. serum ferritin and TSAT, prior to initiating AURYXIA and while on therapy. Patients receiving IV iron may require a reduction in dose or discontinuation of IV iron therapy.

Accidental Overdose of Iron: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6 years of age. Counsel your patients to keep this product out of the reach of children and to call a doctor or poison control center immediately in the case of accidental overdose.

Patients with Gastrointestinal Bleeding or Inflammation: Safety has not been established in these populations.

Adverse Events

The most common adverse events with AURYXIA were diarrhea (21%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%). During the 52-week, active-control period, gastrointestinal adverse reactions were the most common reason for discontinuing AURYXIA (14%).

Special Populations

Pregnancy Category B and Nursing Mothers: It is not known whether AURYXIA can cause fetal harm. However, overdosing of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

Pediatric and Geriatric Use: The safety and efficacy of AURYXIA have not been established in pediatric patients. Overall, the clinical study experience has not identified any obvious differences in responses between the elderly and younger patients in the tolerability or efficacy of AURYXIA.

Overdose

AURYXIA contains iron. Iron absorption from AURYXIA may lead to excessive elevations in iron stores, especially when concomitant IV iron is used. AURYXIA must be kept out of the reach of children. In case of accidental overdose contact a doctor or poison control center immediately.
Drug Interactions

Doxycycline should be taken at least 1 hour before AURYXIA® (ferric citrate). Ciprofloxacin should be taken at least 2 hours before or after AURYXIA. Consider separation of the timing of the administration of AURYXIA with drugs where a reduction in their bioavailability would have a clinically significant effect on safety or efficacy. Monitor blood levels of concomitant medications that have a narrow therapeutic range.

Patient Counseling

Dosing and Administration: Inform patients to take AURYXIA as directed with meals and adhere to their prescribed diets. Instruct patients on concomitant medications that should be dosed apart from AURYXIA.

Adverse Reactions: Advise patients that AURYXIA may cause discolored (dark) stools, which is considered normal with oral medications containing iron. Advise patients to report severe or persistent gastrointestinal symptoms to their physician.