
Memorandum

NDA 21-135/S-024/SDN 355
Submission Date: 7 September 2011
Brand Name: Venofer®
Generic Name: Iron Sucrose Injection, USP
Formulation: 20 mg/mL sterile solution for injection
OCP Reviewers: Bahru A Habtemariam, Pharm.D.
OCP Team Leader: Julie Bullock, Pharm.D.
OCP Division: Division of Clinical Pharmacology V
OND Division: Division of Hematology Products
Sponsor: Luitpold Pharmaceuticals
Submission Type; Code: Original/000; 4F
Dosing regimen: 100 or 200 infusion over 2-5 minutes; 300 over 1.5 hours; 400 mg infused over 2.5 hours.
Indications Treatment of iron deficiency anemia in patients with chronic kidney disease

The sNDA (21-135) for Venofer® (Iron Sucrose Injection, USP) was submitted on 09/07/2011 to expand the indication to children ages 2 years old and above. In the current submission, the sponsor submitted efficacy data and revised labeling. Pediatric PK data were submitted previously on April 19, 2010 to address the pediatric PMR issued on 6/17/05. The pediatric PK data were reviewed previously and the review was posted in DARRTS on 04/08/2011. It was concluded that the pediatric PK data fulfilled the pediatric PMR as outlined below:

1.1 RECOMMENDATIONS

The Office of Clinical Pharmacology finds the study submitted by the applicant to be acceptable in fulfilling the pediatric post marketing requirement #1 (NDA 21-355) outlined in the 6/17/05 approval letter as described below:

1. Deferred pediatric study under PREA for a pharmacokinetic study of Venofer administration to adolescent non-dialysis dependent chronic kidney disease (NDD-CKD) patients, ≥ 12 years to < 16 years of age, receiving or not receiving erythropoietin. Final Report Submission: December 31, 2010

Action

No Action necessary.

Reviewer: Bahru A Habtemariam, Pharm.D.
Division of Clinical Pharmacology 5

Team Leader: Julie Bullock, Pharm.D.
Division of Clinical Pharmacology 5

Cc: DDOP: CSO - **T Scott**; MTL - **K Robie-Suh**; MO - **M Lu**
DCP-5: Reviewer - **B Habtemariam**, TL - **J Bullock**, DDD - **B Booth**,
DD - **A Rahman**;

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/s/

BAHRU A HABTEMARIAM
09/06/2012

JULIE M BULLOCK
09/06/2012