EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Fexeric

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
PSUSA/10418 /201903	Periodic Safety Update EU Single assessment - ferric citrate coordination complex	03/10/2019	n/a		PRAC Recommendation - maintenance
T/0015	Transfer of Marketing Authorisation	21/08/2019	09/09/2019	SmPC, Labelling and PL	
PSUSA/10418 /201809	Periodic Safety Update EU Single assessment - ferric citrate coordination complex	11/04/2019	n/a		PRAC Recommendation - maintenance

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

PSUSA/10418 /201803	Periodic Safety Update EU Single assessment - ferric citrate coordination complex	04/10/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10418 /201709	Periodic Safety Update EU Single assessment - ferric citrate coordination complex	12/04/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10418 /201703	Periodic Safety Update EU Single assessment - ferric citrate coordination complex	26/10/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10418 /201609	Periodic Safety Update EU Single assessment - ferric citrate coordination complex	06/04/2017	n/a		PRAC Recommendation - maintenance
IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	12/10/2016	07/09/2017	SmPC and Annex II	
PSUSA/10418 /201603	Periodic Safety Update EU Single assessment - ferric citrate coordination complex	29/09/2016	n/a		PRAC Recommendation - maintenance
IB/0005/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary	12/06/2016	n/a		

	packaging, for non-sterile medicinal products B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size				
IA/0004	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	11/03/2016	n/a		
IA/0003/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size	08/02/2016	n/a		
IAIN/0002/G	This was an application for a group of variations.	22/12/2015	n/a		

	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition				
IA/0001/G	This was an application for a group of variations. B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	04/12/2015	n/a		