Feraccru

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
IB/0046/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	15/12/2023		SmPC	

[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).

	(supported by real time data)				
PSUSA/10476 /202302	Periodic Safety Update EU Single assessment - ferric maltol	28/09/2023	n/a		PRAC Recommendation - maintenance
IB/0044	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	08/12/2022		SmPC	
PSUSA/10476 /202202	Periodic Safety Update EU Single assessment - ferric maltol	29/09/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10476 /202108	Periodic Safety Update EU Single assessment - ferric maltol	10/03/2022	n/a		PRAC Recommendation - maintenance
IB/0042	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	09/02/2022	13/06/2022	SmPC, Labelling and PL	
IB/0041	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	09/02/2022	13/06/2022	SmPC, Labelling and PL	
IA/0040	B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	13/12/2021	n/a		
IA/0039	A.7 - Administrative change - Deletion of manufacturing sites	02/12/2021	n/a		

PSUSA/10476 /202102	Periodic Safety Update EU Single assessment - ferric maltol	30/09/2021	n/a		PRAC Recommendation - maintenance
IA/0037/G	This was an application for a group of variations. 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 A.7 - Administrative change - Deletion of manufacturing sites B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	13/09/2021	n/a		
IB/0036	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	06/08/2021	13/06/2022	SmPC, Labelling and PL	
IB/0035/G	This was an application for a group of variations. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	02/06/2021	13/06/2022	SmPC, Annex II and PL	

	B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.II.a.3.b.6 - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level				
IB/0032/G	This was an application for a group of variations. 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 A.7 - Administrative change - Deletion of manufacturing sites	15/04/2021	13/06/2022	Annex II and PL	
PSUSA/10476 /202008	Periodic Safety Update EU Single assessment - ferric maltol	11/03/2021	n/a		PRAC Recommendation - maintenance
IAIN/0031	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	22/01/2021	13/06/2022	SmPC and PL	
R/0027	Renewal of the marketing authorisation.	17/09/2020	25/11/2020	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Feraccru in the approved indication remains favourable and therefore recommended the renewal of the marketing

					authorisation with unlimited validity.
IA/0029/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.4 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material) B.III.1.a.4 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)	20/11/2020	n/a		
PSUSA/10476 /202002	Periodic Safety Update EU Single assessment - ferric maltol	01/10/2020	n/a		PRAC Recommendation - maintenance
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/09/2020	25/11/2020	PL	

PSUSA/10476 /201908	Periodic Safety Update EU Single assessment - ferric maltol	12/03/2020	n/a		PRAC Recommendation - maintenance
IA/0025/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	17/12/2019	n/a		
II/0022	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	14/11/2019	16/12/2019	SmPC	
PSUSA/10476 /201902	Periodic Safety Update EU Single assessment - ferric maltol	19/09/2019	22/11/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10476/201902.
PSUSA/10476 /201808	Periodic Safety Update EU Single assessment - ferric maltol	14/03/2019	n/a		PRAC Recommendation - maintenance
T/0020	Transfer of Marketing Authorisation	11/12/2018	31/01/2019	SmPC, Labelling and	

				PL	
IB/0017/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 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.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	23/10/2018	31/01/2019	Annex II, Labelling and PL	
IA/0018/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new/updated or	04/10/2018	n/a		

	deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
PSUSA/10476 /201802	Periodic Safety Update EU Single assessment - ferric maltol	06/09/2018	n/a		PRAC Recommendation - maintenance
IA/0016/G	This was an application for a group of variations. B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	26/07/2018	n/a		

	B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer				
IB/0015	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	15/06/2018	31/01/2019	SmPC	
II/0010	Extension of indication to widen the indication for Feraccru, from the treatment "in adults with Iron deficiency anaemia in patients with IBD" to the treatment of "adults with Iron deficiency". As a consequence, sections 4.1, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet and RMP (v.8) have been updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	22/02/2018	23/03/2018	SmPC and PL	Please refer to the published Assessment Report Feraccru H-2733-II-10-AR.
PSUSA/10476 /201708	Periodic Safety Update EU Single assessment - ferric maltol	08/03/2018	n/a		PRAC Recommendation - maintenance
IAIN/0013/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of	14/12/2017	n/a		

	manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
IB/0012/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.d - Change in batch size (including batch size ranges) of AS or intermediate - More than 10-fold increase compared to the originally approved batch size B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	14/12/2017	n/a		
IB/0009/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	02/10/2017	n/a		

	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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.3.d - Change in batch size (including batch size ranges) of AS or intermediate - More than 10-fold increase compared to the originally approved batch size B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation				
PSUSA/10476 /201702	Periodic Safety Update EU Single assessment - ferric maltol	28/09/2017	n/a		PRAC Recommendation - maintenance

N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/06/2017	23/03/2018	PL	
PSUSA/10476 /201608	Periodic Safety Update EU Single assessment - ferric maltol	09/03/2017	n/a		PRAC Recommendation - maintenance
IA/0006/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	06/02/2017	n/a		
IA/0005/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test B.II.b.3.a - Change in the manufacturing process of	05/01/2017	n/a		

	the finished or intermediate product - Minor change in the manufacturing process				
II/0002/G	This was an application for a group of variations. Submission of two final study reports for in vitro studies conducted as part of post-authorisation measures MEA 001 and MEA 002: - One drug-drug interaction study to investigate drug interactions with Feraccru - One drug-drug interaction study to identify UGT isoenzyme(s) that are responsible for metabolism of ferric maltol. Sections 4.5 and 5.2 of the SmPC and the RMP have been updated to reflect the completion and results of the studies. The variation leads to amendments to the Summary of Product Characteristics and to the Risk Management Plan. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	15/12/2016	16/05/2017	SmPC	With the present variation the MAH has submitted two in vitro studies, one to investigate the effect of Feraccru on the permeability of drugs known to interact with ferrous products (Study CYP0747 R3), and a second study (XenoGesis Study no. 2015_06_23, 2015) conducted to determine the UGT isoenzyme(s) responsible for the glucuronidation of the maltol component of ST10. The product information has been amended to reflect that maltol is glucuronised through UGT1A6 and by sulphation. It is not known if medical products that inhibit UGT enzymes have the potential to increase maltol concentration, but the possibility of an interaction of other drugs that inhibit UGT enzymes cannot be ruled out.
IB/0003	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	06/09/2016	16/05/2017	SmPC	

IAIN/0001	A.1 - Administrative change - Change in the name and/or address of the MAH	11/05/2016	16/05/2017	SmPC, Labelling and PL	