Intrarosa

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
PSR/S/0044	Post Authorisation Safety Study results - EMEA/H/C/PSR/S/0044 – Variation	12/10/2023	07/12/2023	SmPC, Annex II and PL	Intrarosa (prasterone) is removed from the additional monitoring list as the condition to the marketing authorisation has been fulfilled. This relates to the non-interventional PASS - Drug Utilisation Study (DUS) to describe the baseline characteristics, utilisation patterns of EU postmenopausal women initiating treatment with Intrarosa and to assess whether EU prescribers abide by the contraindications stated in the EU 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).

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

					Therefore, the statement that this medicinal product is subject to additional monitoring and that this will allow quick identification of new safety information, preceded by an inverted equilateral black triangle, is removed from the summary of product characteristics and the package leaflet.
IA/0024/G	This was an application for a group of variations. 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 B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	30/10/2023	n/a		
IA/0023	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	24/10/2022	n/a		
R/0022	Renewal of the marketing authorisation.	21/07/2022	15/09/2022	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Intrarosa in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10672 /202111	Periodic Safety Update EU Single assessment - prasterone (vaginal use/Pessary)	10/06/2022	n/a		PRAC Recommendation - maintenance

IB/0020	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	07/03/2022	n/a		
IB/0018	To update the RMP with the final amended protocol of the non-interventional PASS - Drug Utilisation Study. Annex IID is updated accordingly. In addition minor changes have been introduced in the RMP to reflect previous approvals in other variations. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	20/01/2022	15/09/2022	Annex II	
IA/0019/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) 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)	14/01/2022	n/a		
II/0015	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS -	16/12/2021	n/a		

	Introduction of a manufacturer of the AS supported by an ASMF				
PSUSA/10672 /202105	Periodic Safety Update EU Single assessment - prasterone (vaginal use/Pessary)	02/12/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10672 /202011	Periodic Safety Update EU Single assessment - prasterone (vaginal use/Pessary)	10/06/2021	n/a		PRAC Recommendation - maintenance
IB/0014	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	29/01/2021	n/a		
PSUSA/10672 /202005	Periodic Safety Update EU Single assessment - prasterone (vaginal use/Pessary)	14/01/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10672 /201911	Periodic Safety Update EU Single assessment - prasterone (vaginal use/Pessary)	11/06/2020	n/a		PRAC Recommendation - maintenance
IA/0011/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.d.1.b.1 - Stability of AS - Change in the storage conditions - Change to more restrictive storage conditions of the AS	17/01/2020	n/a		

PSUSA/10672 /201905	Periodic Safety Update EU Single assessment - prasterone (vaginal use/Pessary)	28/11/2019	n/a		PRAC Recommendation - maintenance
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/11/2019	01/04/2020	PL	
IB/0008/G	This was an application for a group of variations. 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.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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - 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 B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	05/09/2019	n/a		

	site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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				
PSUSA/10672 /201811	Periodic Safety Update EU Single assessment - prasterone (vaginal use/Pessary)	14/06/2019	n/a		PRAC Recommendation - maintenance
IAIN/0007	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	17/05/2019	n/a		
IAIN/0006/G	This was an application for a group of variations. A.6 - Administrative change - Change in ATC Code/ATC Vet Code B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	16/04/2019	01/04/2020	SmPC	
T/0005	Transfer of Marketing Authorisation	05/02/2019	11/03/2019	SmPC, Labelling and PL	
PSUSA/10672 /201805	Periodic Safety Update EU Single assessment - prasterone (vaginal use/Pessary)	29/11/2018	n/a		PRAC Recommendation - maintenance

IA/0003/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	04/10/2018	n/a		
IAIN/0002/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.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	04/10/2018	11/03/2019	Annex II and PL	