Esperoct

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
II/0023	Extension of indication to include children below 12 years of age for treatment and prophylaxis of bleeding with haemophilia A for Esperoct, including previously untreated patients (PUPs) based on the final results from studies 3776, 4410, 3908, 3859, 3885, 3860, 4033 and 4595. As a consequence,	19/09/2024	21/10/2024	SmPC and PL	Please refer to Scientific Discussion Esperoct H-C-004883/II/0023

[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).

	section 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 3.1 of the RMP has also been submitted. Furthermore, the PI is brought in line with the latest QRD template version 10.4. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
II/0024/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	25/07/2024	n/a		

R/0022	Renewal of the marketing authorisation.	14/12/2023	09/02/2024	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Esperoct in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10782 /202306	Periodic Safety Update EU Single assessment - turoctocog alfa pegol	11/01/2024	n/a		PRAC Recommendation - maintenance
II/0020/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	05/10/2023	n/a		
X/0016	Annex I_2.(c) Change or addition of a new strength/potency	20/07/2023	15/09/2023	SmPC, Labelling and PL	

WS/2480	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	13/07/2023	n/a		
PSUSA/10782 /202212	Periodic Safety Update EU Single assessment - turoctocog alfa pegol	06/07/2023	n/a		PRAC Recommendation - maintenance
II/0013	Update of section 4.2 of the SmPC in order to delete the statement in reference to previously untreated patients (PUPs) and section 5.1 of the SmPC in order to update information based on final results from study NN7088-3908; this is an open-label single-arm multicentre non-controlled phase 3a trial investigating safety and efficacy of turoctocog alfa pegol (N8-GP) in prophylaxis and treatment of bleeding episodes in previously untreated paediatric patients with severe haemophilia A. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	23/02/2023	24/03/2023	SmPC and PL	Submission of the final results from study NN7088-3908 which is an open-label single-arm multicentre non-controlled phase 3a trial investigating safety and efficacy of turoctocog alfa pegol in prophylaxis and treatment of bleeding episodes in previously untreated paediatric patients with severe haemophilia AUpdate of Section 4.2 to remove the statement. Section 4.2 and 5.1 have been updated accordingly. In addition, information on Factor VIII inhibition as “very common” event in PUPs is included in section 4.8 of the SmPC. Amendments are requested. For more information, please refer to the SmPC.
PSUSA/10782 /202206	Periodic Safety Update EU Single assessment - turoctocog alfa pegol	12/01/2023	n/a		PRAC Recommendation - maintenance

IB/0017/G	This was an application for a group of variations. B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol B.II.f.1.e - Stability of FP - Change to an approved stability protocol	30/11/2022	24/03/2023	SmPC	PI was updated to reflect extension of the shelf life of the finished product Esperoct® unopened vial, before reconstitution from 30 months to 36 months when stored at 5°C.
IB/0014	B.II.h.z - Adventitious Agents Safety - Other variation	12/08/2022	n/a		
II/0010	Update of sections 4.4 and 4.8 of the SmPC to add a new warning and update the list of ADRs based on a validated safety signal concerning a lack of factor VIII activity in patients switching from a similar factor VIII product to Esperoct. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to align it with the latest QRD template version 10.2. The RMP version 2.1 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	21/07/2022	24/03/2023	SmPC, Labelling and PL	Update of sections 4.4 and 4.8 of the SmPC to add a new warning and update the list of ADRs based on a validated safety signal concerning a lack of factor VIII activity in patients switching from a similar factor VIII product to Esperoct. For more information, please refer to the Summary of Product Characteristics.
PSUSA/10782 /202112	Periodic Safety Update EU Single assessment - turoctocog alfa pegol	07/07/2022	n/a		PRAC Recommendation - maintenance
WS/2227	This was an application for a variation following a worksharing procedure according to Article 20 of	02/06/2022	n/a		

	Commission Regulation (EC) No 1234/2008. 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				
WS/2136	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.c.1.c - Change in immediate packaging of the AS - Liquid ASs (non sterile)	28/04/2022	n/a		
PSUSA/10782 /202106	Periodic Safety Update EU Single assessment - turoctocog alfa pegol	13/01/2022	n/a		PRAC Recommendation - maintenance
PSUSA/10782 /202012	Periodic Safety Update EU Single assessment - turoctocog alfa pegol	08/07/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10782 /202006	Periodic Safety Update EU Single assessment - turoctocog alfa pegol	14/01/2021	n/a		PRAC Recommendation - maintenance
IB/0006	B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation	07/01/2021	n/a		
IB/0004	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/08/2020	25/08/2020	SmPC and PL	

PSUSA/10782 /201912	Periodic Safety Update EU Single assessment - turoctocog alfa pegol	09/07/2020	n/a		PRAC Recommendation - maintenance
II/0002	B.II.f.1.c - Stability of FP - Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol	30/01/2020	25/08/2020	SmPC, Labelling and PL	
WS/1681	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	17/10/2019	n/a		