Ngenla

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type II /	Outcome:	02/07/2026		SmPC and PL	Post-marketing cases of epiphysiolysis associated

[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).

EMA/VR/0000333019	C. Safety, efficacy, pharmacovigilance changes - C.4 Change(s) in the summary of product characteristics, labelling or package leaflet due to new quality, preclinical, clinical or pharmacovigilance data. - Accepted Update of sections 4.4 and 4.8 of the SmPC in order to amend an existing warning on epiphyseal disorders, and to add 'epiphysiolysis (including slipped capital femoral epiphyses)' to the list of adverse drug reactions (ADRs) with frequency not known, based on a cumulative safety review. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor updates to the PI.				with somatrogon use have been reported. For more information, please refer to the Summary of Product Characteristics.
Variation type IA_IN / EMA/VR/0000315819	Outcome: C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Change(s) in the Summary of product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a PRAC signal recommendation: implementation of wording agreed by the competent authority that do not require any further assessment - Accepted	16/12/2025	19/06/2026	SmPC and PL	To update sections 4.2 and 4.8 of the SmPC and sections 3 and 4 of the PL to implement the signal recommendations on 'Somatrogon – Lipoatrophy (EPITT no 20173)' adopted at the 4 September 2025 PRAC.
Variation type II / EMA/VR/0000281283	Outcome: B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active	11/09/2025			

	substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted				
Variation type IA / EMA/VR/0000266074	Outcome: This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier) - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality	23/04/2025	19/06/2026	Annex II	

	control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted				
PSUR / EMA/PSUR/0000248527	EURD: PSUSA/00010982/202410 Active substance: somatrogon Outcome: Maintenance	05/06/2025			Based on the PRAC review of data on safety and efficacy, the PRAC considers that the risk-benefit balance of medicinal products containing somatrogon remains unchanged and therefore recommends the maintenance of the marketing authorisation(s).