Quadramet

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 / EMA/VR/0000246157	This was an application for a group of variations.	04/09/2025		SmPC, Labelling and	SmPC new text An extensive review of the document takes place as the MAH took opportunity

[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).

	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted A grouped application consisting of: C.I.4: Update of section 4.4 of the SmPC in order to add a new warning on extravasation based on the new literature data; in addition, the MAH took opportunity to align clinical pharmacology, efficacy, and safety data with the current guidelines; the Package Leaflet and Labelling are updated accordingly. C.I.4: Update of section 4.8 of the SmPC in order to add dizziness, bone pain and asthenia to the list of adverse drug reactions (ADRs) with frequency common and anorexia with frequency uncommon based on the clinical trial data; the Package Leaflet is updated accordingly.			PL	to align clinical pharmacology, efficacy, and safety data with the current guidelines. As per the scope of the grouped variations the following changes were performed: Section 4.4: Under specific warnings the following is added: "Paravenous injection must be avoided due to the risk of local tissue necrosis. Injection should be strictly intravenous to avoid local deposit and irradiation. In the event of paravenous injection, the injection should be immediately stopped and the site of injection should be warmed and rested in elevated position. When radiation necrosis occurs, surgical intervention may be necessary." Section 4.8: Dizziness, bone pain and asthenia are added to the list of adverse drug reactions (ADRs) with frequency common and anorexia with frequency uncommon For more information, please refer to the Summary of Product Characteristics.