Qutenza

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 /	C.I HUMAN AND VETERINARY MEDICINAL	12/02/2026		SmPC and PL	Update of sections 4.2, and 5.1 of the SmPC in

[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/0000294536	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 Update of sections 4.2, and 5.1 of the SmPC in order to improve the instructions to healthcare professionals and patients based on RWE from the CASPAR study; this is a is a non-interventional, retrospective, multi-cohort study, where real-world data from the German Pain e-Registry (GPeR) is being used to investigate the effect of Qutenza treatment administered up to 4 times over a period of 12 months. The Package Leaflet is updated accordingly.				order to improve the instructions to healthcare professionals and patients based on RWE from the CASPAR study; this is a is a non-interventional, retrospective, multi-cohort study, where real-world data from the German Pain e-Registry (GPeR) is being used to investigate the effect of Qutenza treatment administered up to 4 times over a period of 12 months. The Package Leaflet is updated accordingly.
Variation type IA / EMA/VR/0000322699	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	16/01/2026			