Onureg

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 IA / EMA/VR/0000315025	B.I.a.4 Change to in-process tests or limits applied during the manufacture of the active substance - B.I.a.4.c Deletion of a non-	18/12/2025	N/A		

[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).

	significant in-process test - Accepted 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				
Renewal - 5 year / EMA/R/0000289529	- Renewal - Accepted Renewal of marketing authorisation	13/11/2025	08/01/2026	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Onureg in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. In the frame of this renewal and as a result of analysis of Serious Adverse Events, section 4.8 has been updated to include ADRs for sepsis and neutropenic sepsis with a common and uncommon frequency respectively
Variation type IB / EMA/VR/0000291593	C.I.3 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of human medicinal products intended to implement the outcome of a procedure concerning PSUR or PASS, or the outcome of the assessment done by the competent	14/10/2025	08/01/2026	SmPC and PL	To include the adverse reaction "differentiation syndrome" in sections 4.4 and 4.8 of the SmPC following the assessment in EMEA/H/C/PSUSA/00010935/202405. The package leaflet is updated accordingly. In addition the MAH has amended the wording for tabulated list of

	authority under Articles 45 or 46 of Regulation 1901/2006 - C.I.3.z Other variation - Accepted To include the adverse reaction "differentiation syndrome" in sections 4.4 and 4.8 of the SmPC following the assessment in EMEA/H/C/PSUSA/00010935/202405. The package leaflet is updated accordingly. In addition the MAH has amended the wording for tabulated list of adverse reactions in section 4.8 of the SmPC.				adverse reactions in section 4.8 of the SmPC.
Article 61(3) / EMA/N/0000245924	- - Accepted Update of the package leaflet to introduce a list of local representatives.	17/02/2025	08/01/2026	PL	