# Public Assessment Report

# Update

# Rivaroxaban Medreg
# Rivaroxaban

# SK/H/0279/001-004/DC

**This module reflects the procedural steps and scientific information after the finalisation of the initial procedure.**

| Procedure number* | Scope | Product Information affected | Date of end of procedure | Approval/ non approval | Summary/ Justification for refuse |
|---|---|---|---|---|---|
| *SK/H/0279/001-004/IA/001* | IA<br>C.I.3.a<br><br>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 authority under Articles 45 or 46 of Regulation 1901/2006 - Implementation of wording agreed by the competent authority | SmPC and PL<br><br>Adding an adverse effect: Anticoagulant-related nephropathy to section 4.8 SmPC and section 4 PL | 07 January 2024 | approved | |
| *SK/H/0279/001-004/IB/002/G* | IB<br>A.2.b<br><br>ADMINISTRATIVE CHANGES - Change in the (invented) name of the medicinal product - for Nationally Authorised Products<br><br>IAIN<br>C.I.8.a<br><br>SAFETY, EFFICACY, PHARMACOVIGILANCE CHANGES - HUMAN AND VETERINARY MEDICINAL PRODUCTS - Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use* - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location | Changes in CMS Romania | 10 February 2024 | approved | |
| *SK/H/0279/003-004/IA/003* | IAIN<br>B.II.e.5.a.1<br><br>QUALITY CHANGES - FINISHED PRODUCT - Container closure system - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes | SmPC, PL, and labelling<br><br>Addition of 30 film-coated tablets pack size for 15 mg and 20 mg. | 10 February 2024 | approved | |
| *SK/H/0279/001-004/IA/004* | IA<br>A.5.b<br><br>ADMINISTRATIVE CHANGES - Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - The activities for which the manufacturer/importer is responsible do not include batch release | Update the address of the manufacturer of the finished product. | 19 July 2024 | approved | |

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| *SK/H/0279/001-004/IB/005* | IB<br>C.I.z<br>Submission of ERA in line with the current Guideline on the environmental risk assessment of medicinal products for human use (EMEA/CHMP/SWP/4447/00 corr 2) as postapproval commitment from DCP procedure no. SK/H/0279/001-004/DC. | Fulfilment of a postapproval commitment after EoP. | 09 November 2024 | approved | |

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)