



RIVAROXABAN – reliable absorption Capsules

- **Indicated for** the prevention and treatment of deep vein thrombosis, stroke, pulmonary embolism, and other thromboembolic events.
- **Posology:** All strengths can be taken irrespective of food intake. The reference product, available in 15mg and 20mg strengths, must be taken with food; otherwise, there is a risk of low absorption levels.

No restrictions apply to the higher strengths (15mg and 20mg) – both can be taken with or without food

Guaranteed Efficacy:
This product offers a lower risk of complications such as stroke or embolism, making it a reliable choice for patients

All strengths available: 15mg and 20mg with food-independence

Innovative formulation

- The proprietary API intermediate and enhanced formulation properties of this product eliminate food dependence, allowing for administration regardless of meal intake.

Guaranteed Efficacy for Patients:

- The systemic plasma concentration of this product can be achieved with or without food.
- Unlike the original Rivaroxaban, which has been reported to increase thromboembolic events when taken on an empty stomach (based on a warning from MHRA, UK), this value-added product ensures a lower risk of complications such as stroke or embolism.
- Increased patient compliance is expected due to administration regardless of food intake, providing better convenience.
- Additionally, this approach lowers the risk of medication errors.

Innovative formulation

Regulatory pathway

- Reference medicinal product: Xarelto, film-coated tablets from Bayer
- Legal basis: Article10(3) hybrid application
- Scientific advice successfully passed

Development status

- The proof of concept study has been successfully completed
- Results from the pivotal bio-equivalency study are expected in Q2/2025
- The EU dossier is anticipated to be completed by Q3/2025

Partnership options

- The product is available for out-licensing in select European markets
- The product is also available for licensing outside of Europe

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