



RIVAROXABAN – food independent Capsules

- **Indicated for** prevention and treatment of deep vein thrombosis, stroke, pulmonary embolism and other thromboembolic events
- **Posology:** All strengths can be taken irrespective of food.
Current reference product: 15mg and 20mg have to be taken with food, otherwise risk of low level of absorption

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

Guaranteed efficacy, lower risk of complications such as stroke or embolism

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

Innovative formulation

- Food dependence eliminated due to proprietary API properties and an enhanced formulation

Guaranteed efficacy for patients

- Required systemic plasma concentration achieved also without food
- Standard Rivaroxaban has been reported to increase thromboembolic events when taken on empty stomach (based on warning from MHRA, UK)*
- Lower risk of complications such as stroke or embolism of the value added product, as absorption guaranteed

Increased patient compliance expected

- Administration regardless of meal giving patients better convenience
- Lowers risk of medication errors

Innovative formulation

* <https://www.gov.uk/drug-safety-update/rivaroxaban-xarelto-reminder-that-15-mg-and-20-mg-tablets-should-be-taken-with-food>

Regulatory pathway

- Reference medicinal product: Xarelto, film-coated tablets from Bayer
- Legal basis: Article 10(3) hybrid application
- Scientific advice successfully passed

Development status

- Proof of concept study successfully done
- Pilot bio-equivalency study results available from Q3/2021
- EU dossier expected to be completed by Q1/2024

Partnership options

- Product is available for out-licensing in selected markets in Europe
- Dossier can be adjusted to markets outside Europe based on request

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