**EDUCATIONAL MATERIALS**

**Dissemination of educational materials for**

**Apixaban 2.5 mg and 5 mg Film-coated Tablets**

**PL 43461/0208-0209**

## Distribution Plan for Apixaban Educational Materials

| COMMUNICATION PLAN | |
|---|---|
| Medicinal product(s) | Apixaban 2.5 mg Film-coated Tablets<br>Apixaban 5 mg Film-coated Tablets |
| Active substance(s) | Apixaban |
| Marketing authorisation holder(s) | Flamingo Pharma (UK) Limited<br>1st floor, Kirkland House<br>11-15 Peterborough Road<br>Harrow<br>HA1 2AX<br>United Kingdom |
| Safety concern and purpose of the communication | Important identified risks<br>• Bleeding<br>Important potential risks<br>• Liver Injury<br>• Potential risk of bleeding or thrombosis due to overdose or underdose<br>Missing information<br>• Use in patients with severe renal impairment |
| Approval date of Educational Materials / RMP version number | • Approval date of RMP: 06-Oct-2026<br>• RMP Version number: 1.0 |
| Target audience and planned distribution path including recipients of educational materials | **Patient Alert Card**<br>The MAH shall distribute "Patient Alert Card" to patients or caretaker of patients. A copy of the Patient Alert Card shall be provided in the carton for Apixaban 2.5 mg, and 5 mg film coated Tablets |
| Member States / Country where the Educational Materials will be distributed | UK-wide |
| Dissemination mode | Digital: placing on web-site<br>https://www.medicines.org.uk/emc<br>Paper copy: A printed copy of the approved Patient Alert Card will be provided upon request. |

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| Dissemination of educational materials | MAH shall distribute the above-mentioned educational materials prior to launch of the product as per the regulatory requirement. |