

## EDUCATIONAL MATERIALS

### Dissemination of educational materials for

### Rivaroxaban Umedica 2.5 mg, 10 mg, 15 mg and 20 mg film-coated tablets

PL 60528/0016-0019

#### Distribution Plan for Rivaroxaban Umedica Educational Materials

Medicinal product(s)	Rivaroxaban Umedica 2.5 mg film-coated tablets Rivaroxaban Umedica 10 mg film-coated tablets Rivaroxaban Umedica 15 mg film-coated tablets Rivaroxaban Umedica 20 mg film-coated tablets
Active substance(s)	Rivaroxaban
Marketing authorisation holder(s)	Umedica Laboratories UK Ltd Office No. G42, The Panorama Park Street Ashford, England TN24 8DF
Safety concern and purpose of the communication	Important identified risk - Haemorrhage
Target audience and planned distribution path including recipients of educational materials	<b><u>Prescriber Guide</u></b> The MAH shall make the "Prescriber Guide" available electronically on an electronic medicines compendium (eMC) website or a non-promotional company website, for all the physician and other healthcare professionals who may prescribe rivaroxaban. Hard copies of the educational material shall be made available on request.  <b><u>Patient Card</u></b> The MAH shall distribute "Patient Card" to patients or care taker of patients. A copy of the Patient Card shall be provided in the carton for Rivaroxaban Umedica 2.5mg, 10mg, 15mg and 20mg Filmcoated Tablets.
Member States / Country where the Educational Materials will be distributed	UK-wide
Dissemination mode	Digital: placing on web-site <a href="https://www.medicines.org.uk/emc">https://www.medicines.org.uk/emc</a> Paper copy: on request.
Dissemination of educational materials	MAH shall distribute the above-mentioned educational materials prior to launch of the product as per the regulatory requirement.