Rivaroxaban Risk Minimisation Material

MAH is distributing material intended to minimise the risk of treatment of Rivaroxaban.

Rivaroxaban 2.5mg is indicated for the following:

- Prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events (when co-administered with acetylsalicylic acid (ASA)
- Prevention of atherothrombotic events in adults after an acute coronary syndrome (ACS)
 with elevated cardiac biomarkers (when co-administered with acetylsalicylic acid (ASA) plus
 clopidogrel or ticlopidine)

For authorised indications of Rivaroxaban please refer to the electronic medicines compendium at www.medicines.org.uk/emc

Under the terms of Marketing Authorisation, the MAHs are mandated to provide all healthcare professionals (HCPs) who are likely to treat patients with Rivaroxaban.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. You, as a Healthcare Professional, are asked to report any adverse reactions via the national reporting system. Please report any suspected adverse reactions to any medicine to the MHRA via the Yellow Card Scheme. You can report via the Yellow Card Website: www.mhra.gov.uk/yellowcard The free Yellow Card app is available from the Apple App Store or Google Play Store. Some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals.

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

Company Contact point: If you require further information about Rivaroxaban, further copies of these materials or have any questions please contact the relevant MAH

The SmPC, Patient Information Leaflet and the risk minimisation measures are also available at www.medicines.org.uk/emc.

Yours sincerely,