

Lixiana®▼ (Edoxaban): risk minimisation resources

June 2015

Dear Healthcare Professional,

Summary

- Edoxaban is an oral anticoagulant that acts by direct selective inhibition of factor Xa
- Please familiarise yourself with the following educational materials before prescribing edoxaban as they contain important safety information:
 - Prescriber Guide – for healthcare professionals
 - Patient Alert Card – for patients (inserted into the packs)
 - Summary of Product Characteristics – for healthcare professionals
- Ensure all patients familiarise themselves with the Patient Alert Card found in their pack before starting treatment. Advise them on the:
 - signs or symptoms of bleeding and when to seek attention from a healthcare professional
 - importance of treatment compliance
 - need to carry the Patient Alert Card with them at all times
 - need to inform healthcare professionals that they are taking edoxaban if they need to have any surgery or invasive procedure

Indication

Edoxaban, an oral anticoagulant acting by direct selective inhibition of factor Xa, received European licence on the XXX June 2015 for the:

- prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA)
- treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

Educational materials

As part of the licence, the educational materials listed above have been developed to help manage important risks associated with edoxaban use. Please familiarise yourself with these materials before prescribing edoxaban as they contain important safety information. In particular, they highlight the potential risk of bleeding during treatment and provide guidance on how to manage that risk.

In addition, please ensure that all patients familiarise themselves with the Patient Alert Card found in the pack before starting treatment. Advise them on the key safety messages listed above.

The materials can be accessed from the Electronic Medicines Compendium (eMC)

(<https://www.medicines.org.uk/emc/ingredient/xxxxx/edoxabanTBC>) or by contacting the Daiichi Sankyo Medical Information department (telephone: 08000285122; email: medinfo@daiichi-sankyo.co.uk).

Call for reporting

Please report suspected adverse reactions with any medicine or vaccine to the Medicines and Healthcare Products Regulatory Agency (MHRA) through the Yellow Card Scheme online at <https://yellowcard.mhra.gov.uk/>. Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- at the back of the British National Formulary (BNF)
- by telephoning the Commission of Human Medicines (CHM) free phone line: 0800 731 6789
- or by electronic download through the Yellow Card section of the MHRA website <https://yellowcard.mhra.gov.uk/downloadable-information/>

When reporting, please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Any suspected adverse reactions with edoxaban may also be reported to Daiichi Sankyo UK via telephone at 08000285122 or via email medinfo@daiichi-sankyo.co.uk.

Company contact point

Should you have any questions regarding the use of edoxaban, please contact Daiichi-Sankyo UK Medical Information via telephone at 08000285122 or via email medinfo@daiichi-sankyo.co.uk.

Yours sincerely,



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