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Prescribing Matters

Milton Keynes Prescribing Advisory Group

Circulation to all GP practices FAO all Clinicians, Community Pharmacists, Hospital and CCG staff

A Newer Oral AntiCoagulant (NOAC) **Rivaroxaban (Xarelto®)**

For treatment of DVT and PE and prevention of recurrent DVT and PE

BNF Category: 2.8.2

NICE TAs 261 and 287

For DVT & PE where warfarin cannot be given Rivaroxaban is the MKPAG recommended NOAC

How can this bulletin help you?

Our aim is to support the safe and effective use of the newer oral anticoagulant drugs (NOACs) across the NHS in Milton Keynes.
This bulletin sets out key information on the use of Rivaroxaban in the management of VTE (DVT & PE)

The MHRA has issued advice about the safe use of the newer oral anticoagulants (dabigatran, rivaroxaban and apixiban). Published October 2013

1. *Unlike vitamin K antagonists (warfarin, phenindione) there is no need for routine monitoring of anticoagulant activity when administering these medicines.*
2. ***However, clinical trials and post-marketing experience have shown that major bleeding events, including events leading to death, are not confined to vitamin K antagonists/LMWH but are also significant risks for the newer oral anticoagulants.***
3. *Furthermore, post-marketing surveillance reports indicate that not all prescribers are sufficiently aware of the product information in terms of managing bleeding risks.*
4. *It is important to pay attention to the recommended posology and the warnings and precautions for use to minimise the risk of bleeding. This includes a careful benefit-risk assessment in patients with lesions, conditions, procedures and/or treatments (such as NSAIDs& antiplatelets), which increase the risk of major bleeding.*
5. ***Clinical surveillance for signs and symptoms of bleeding is recommended throughout the treatment period,***
6. ***Attention should also be paid to renal function including on-treatment deterioration.***

How should I treat DVTs and PEs and prevent further VTEs?

Warfarin remains the first-line oral anticoagulant for most patients.
For DVT and PE first line treatment is low molecular weight heparin followed by warfarin, dose adjusted according to target INR.

MKPAG RECOMMENDATION

The Newer Oral AntiCoagulants (NOACs) are only recommended by NICE to be used as an option, as an alternative to warfarin.
Following extensive discussion with clinicians in both primary and secondary care, **where warfarin cannot be used Rivaroxaban is our locally recommended NOAC for treatment and prevention of Pulmonary Embolism (PE) & Venous Thromboembolism (VTE)**

When could I prescribe Rivaroxaban?

Rivaroxaban is recommended where warfarin is contraindicated or not tolerated, or where INR monitoring is impractical,

Rivaroxaban may be suitable, for patients in whom parenteral anticoagulants e.g. dalteparin are contraindicated or not tolerated as there is no requirement for use of heparin or LMWH at start of therapy.

Elective hip and knee replacement patients receive a full course of Dabigatran from MKHFT for primary prevention of VTE
Do NOT put Dabigatran or Rivaroxaban on repeat prescription for this indication.

Contraindications

- Lesion or conditions considered to be significant risk for major bleeding;
- Concomitant treatment with any other anticoagulants;
- Hepatic disease;
- Pregnancy and breast feeding.

See eMC for further details including management of bleeding or overdose

How safe is Rivaroxaban?

Long term safety and tolerability of Rivaroxaban is not yet known.
There is no specific antidote available.
There are currently no tests to assess the level of compliance or anticoagulation (under or over) being achieved.

Other factors for consideration are:
The patient's current INR on warfarin, other interacting medicines, compliance, renal function, bleeding risks, especially GI bleeding risk.
The effect of non-compliance might be more significant because of NOACs' short half-lives compared to warfarin, and the absence of tests to monitor coagulation levels.

How much does it cost?

NICE estimates that the incidence of diagnosed VTEs in Milton Keynes is approximately 300 each year.
The recommended dose of Rivaroxaban for the initial treatment of acute DVT or PE is 15 mg twice daily for the first three weeks followed by 20 mg once daily
Rivaroxaban is significantly more expensive than therapy with warfarin

Cost comparison for VTE treatment or prevention per annum

Warfarin	Rivaroxaban
£12 **(+ £112 local monitoring costs)**	**£767**

Cost of testing may vary

Clinical trials have shown that we would need to treat 110 patients with Rivaroxaban (instead of warfarin) for 12 months in order to prevent ONE non-fatal VTE event and this would cost the NHS budget **£84,000.**

Warfarin has been in use for over 60 years; its effects are measurable and can be rapidly reversed in event of major bleeding

Glossary of abbreviations
NICE: National Institute for Health and Care Excellence
MHRA: Medicines and Healthcare Products Regulatory Agency
eMC: Electronic Medicines Compendium
DVT: Deep Vein Thrombosis
PE: Pulmonary Embolism

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