

Prescribing tip for information and action

MHRA warning: Rivaroxaban (Xarelto ▼) - reminder that 15 mg and 20 mg tablets should always be taken with food



The Medicines and Healthcare Products Regulatory Agency (MHRA) has received a small number of reports suggesting lack of efficacy (thromboembolic events) in patients taking 15 mg or 20 mg rivaroxaban on an empty stomach.¹

- The Summary of Product Characteristics for **high strength** rivaroxaban 15mg and 20mg tablets state that bioavailability is only 66% on an empty stomach for the 20mg tablets.² Not taking it with food is likely to lead to sub-therapeutic levels of the drug in the blood and subsequently increase the risk of thromboembolic events.
- **In contrast, there is almost complete oral absorption and high bioavailability of rivaroxaban 15mg and 20mg tablets when they are taken with food.**
- N.B. The lower strengths of rivaroxaban 2.5 mg and 10 mg tablets can be taken with or without food as oral absorption of **low strength** rivaroxaban is almost complete and oral bioavailability is high (80 - 100%). These strengths are less commonly prescribed in primary care.

All DOACs have a short half-life and therefore must be taken regularly, as prescribed, in order to be effective. If doses are missed, levels of drug in the blood will quickly become sub-therapeutic.

The importance of good concordance, taking the tablets exactly as prescribed, in order to ensure they remain effective, must be emphasised at every opportunity.

Advice to Prescribers:

- Remind patients to take 15 mg or 20 mg rivaroxaban tablets once daily with food and not to miss doses;
- Ensure the directions of rivaroxaban 15mg or 20mg tablets state one to be taken daily with food;
- For patients who have difficulty swallowing, tablets can be crushed and mixed with water or apple puree immediately before taking; this mixture should be immediately followed by food.

References:

1. Drug Safety Update volume 12, issue 12: July 2019: 3 <https://www.gov.uk/drug-safety-update/rivaroxaban-xarelto-reminder-that-15-mg-and-20-mg-tablets-should-be-taken-with-food> accessed 18/7/19
2. Summary of Product Characteristics for rivaroxaban 15mg tablets <https://www.medicines.org.uk/emc/product/2794/smpc> accessed 18/7/19

To contact the Medicines Optimisation Team please phone 01772 214302