Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Patient, Pharmacy and Wholesaler Level

Date: 28/09/17 EL (17) A/09 Our Ref: MDR 120-09/17

Dear Healthcare Professional,

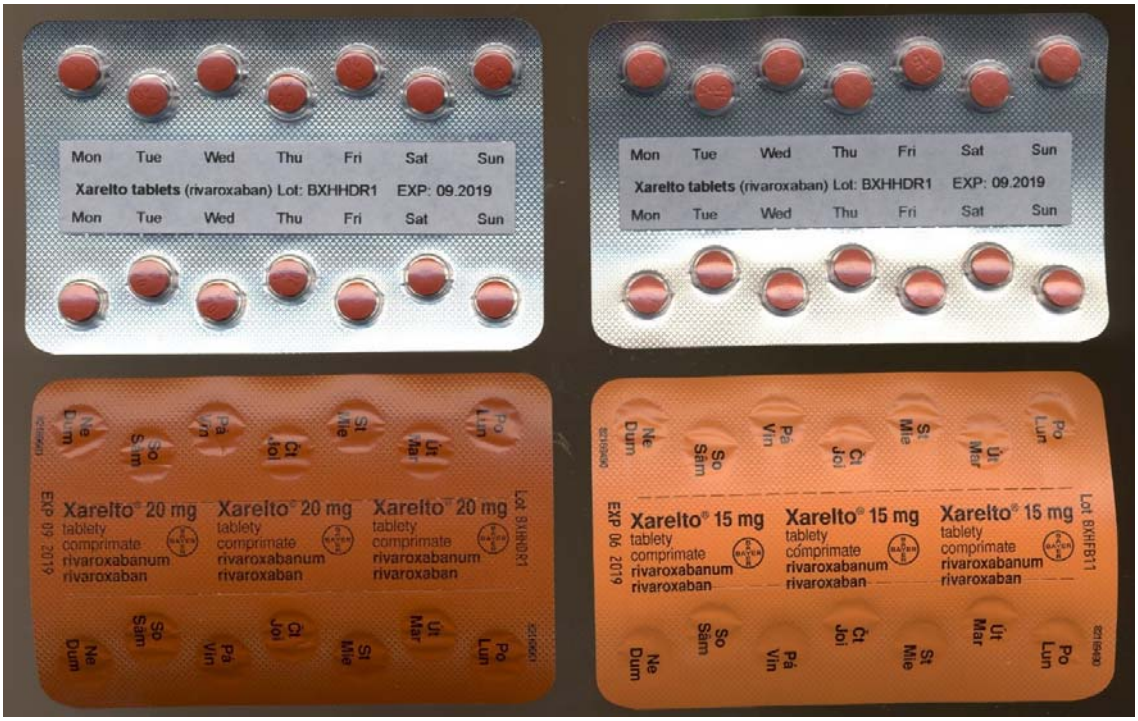
Strathclyde Pharmaceuticals Ltd

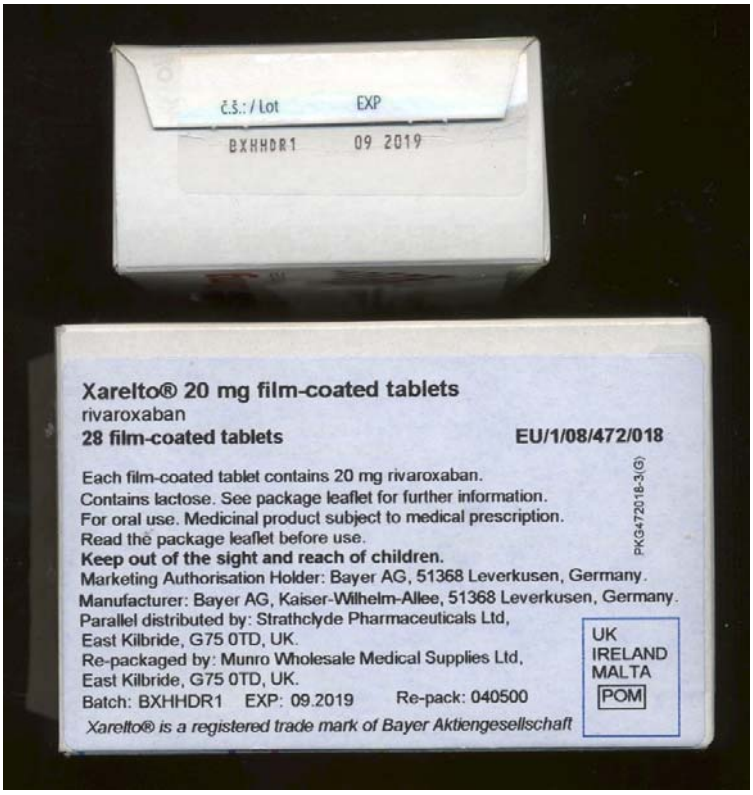
Xarelto 20 mg film-coated tablets EU/1/08/472/018
(Rivaroxaban)

Batch Number	Expiry Date	Pack Size	First Distributed
BXHHDR1	09/2019	28 tablets	18/09/2017

Brief description of the problem

Strathclyde Pharmaceuticals Ltd has received a report of a rogue blister strip of 15 mg tablets within two packs of 20 mg tablets and has decided to recall this batch. The labelling on one side of the blister strips reflects the correct strength of the tablets as shown:





Advice for healthcare professionals

Please take the following actions:

- Quarantine any remaining stock from batch BXHHDR1 and return it to the original supplier.
- Identify patients or carers that have received Strathclyde Pharmaceuticals Ltd Xarelto 20 mg tablets (including in compliance aids) since the 18 September 2017 inclusive.
- Contact these patients or carers to notify them of this issue and to ask them whether the tablets have batch BXHHDR1 printed on any of the packaging.
- Ask patients or carers who have received batch BXHHDR1 to check if any of the blisters or tablets are labelled as 15 mg.
- If the patient or carer finds any of the blisters or tablets labelled as 15 mg, they should be asked to return the tablets to the pharmacy where they were purchased or dispensed. If the tablets and blisters inside the carton are the correct strength of 20 mg, patients or carers do not need to return the tablets to the pharmacy.
- If the patient or carer does have tablets of the incorrect strength, make sure that you provide new supplies of this medicine from other batches. It is important for patients not to interrupt their treatment unless instructed by healthcare professionals.

- If patients have been dispensed Strathclyde Pharmaceuticals Ltd Xarelto 20 mg tablets in compliance aids since 18 September 2017 inclusive, patients or carers should be asked to return the compliance aids to the pharmacy in order to be issued with replacements.

Wholesalers

Wholesalers are requested to return any remaining stock of batch BXHHDR1 to their original supplier for credit.

Patients

If you have received any Xarelto (rivaroxaban) 20 mg tablets since the 18 September 2017 inclusive, please check if BXHHDR1 is printed on any of the packaging.

If BXHHDR1 is printed anywhere on the packaging, check if there are any tablets or blisters in the carton labelled 15 mg. If so, please speak to your healthcare professional as soon as possible about obtaining a replacement pack.

It is important that you do not interrupt your treatment unless instructed by healthcare professionals.

If you have been dispensed Xarelto (rivaroxaban) 20 mg tablets in compliance aids (containers with all the medication for each day of the week) since 18 September 2017 inclusive, please return all your compliance aids to the pharmacy in order to be issued with replacements.

If you experience side-effects, or have any questions or concerns about your health, speak to your doctor, pharmacist, or other healthcare professional. Any suspected side effects can be reported to MHRA through our medicines safety monitoring system, the Yellow Card Scheme or download the Yellow Card App here.

Medical information enquiries For medical information enquiries please contact Julie Cummings on 01355 574450.

Stock enquiries For stock enquiries please contact Shirley Gorrell on 01355 574450.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS regional teams are asked to forward this to relevant clinics, dispensing general practitioners (GPs) and community pharmacists for information.

Yours faithfully

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