MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION, EL(26)A/17

Caution In Use

Issued 26 March 2026

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Sandoz Limited

MEDICINE DETAILS

Apixaban 5mg Tablets

PL: 04416/1608

Active Ingredient: apixaban

SNOMED code: 40640311000001107

GTIN (28 tablets): 07613421102531

GTIN (56 tablets): 07613421102548

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PS2891	30/06/2028	56	19/01/2026
PT0565	30/06/2028	56	16/01/2026
PT1417	31/07/2028	56	19/01/2026
PU0476	31/07/2028	56	15/01/2026
PU0481	31/08/2028	56	15/01/2026
PV5375	31/07/2028	28	Not yet distributed
PW1623	31/07/2028	28	Not yet distributed
PW1624	30/04/2028	28	Not yet distributed

MEDICINE DETAILS

Apixaban 2.5mg Tablets

PL: 04416/1607

Active Ingredient: apixaban

SNOMED code: 40655511000001108

GTIN (10 tablets) 07613421102500

GTIN (20 tablets): 07613421102517

GTIN (60 tablets): 07613421102524

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
PU1963	31/07/2028	60	15/01/2026
PU3287	31/01/2028	20	15/01/2026
PT4596	31/07/2028	60	15/01/2026
PT2868	31/07/2028	60	Not yet distributed
PU2604	31/07/2028	60	Not yet distributed
PU2605	31/07/2028	60	Not yet distributed
PU2606	31/07/2028	60	Not yet distributed
PT1722	30/11/2027	10	Not yet distributed

Background

Sandoz Ltd. have informed the MHRA that the Patient Information Leaflet (PIL) included in the affected batches of Apixaban does not contain up-to-date information relating to:

- The newly authorised paediatric indication (children aged 28 days to <18 years), and
- Updated guidance regarding use following spinal/epidural catheter removal.

The updated PIL wording is shown in Table 1 and will be included in all future manufactured batches.

The batches listed as ‘not yet distributed’ have also been manufactured and packed with the previous PIL version. The MHRA, in discussion with the Department of Health and Social Care, considers these products critical for patients, therefore these batches will not be repackaged and continue to be distributed. They are therefore included in this notification.

All subsequently manufactured batches will include the updated PIL.

Table 1- Summary of the updated safety information missing from the packed PIL:

PIL Section	New PIL Wording (Actual Text)
Section 1 What is Apixaban used for	"Apixaban is used in children aged 28 days to less than 18 years to treat blood clots and to prevent re-occurrence of blood clots in the veins or in the blood vessels of the lungs. For body weight appropriate recommended dose, see section 3."
Section 2 – What you need to know before you take Apixaban Warnings and precautions	"Talk to your doctor, pharmacist or nurse before you take this medicine if you have any of the following: Had a tube (catheter) or an injection into your spinal column (for anaesthesia or pain reduction), your doctor will tell you to take this medicine 5 hours or more after catheter removal".
Section 3 – How to Take Apixaban (Paediatric Dosing)	"Use in children and adolescents… The dose depends on the body weight, and will be calculated by the doctor. Paediatric posology: Two tablets of Apixaban 5 mg twice a day for 7 days, then one tablet twice daily thereafter. Caregivers should observe dosing; scheduled doctor visits may be required to adjust weight-based dose."

Advice for Healthcare Professionals:

Be aware of the updated information regarding the use of Apixaban in children aged 28 days to less than 18 years, and administration at least 5 hours after spinal/epidural catheter removal. Inform patients and carers of the approved dosing advice for children or patients with a catheter fitted.

Upon request, Sandoz Limited will provide hard copies of the updated PIL to wholesalers and pharmacies so that any remaining stock can be supplemented with the correct PIL information. To request hard copies of the PIL, please contact sales.sandoz-gb@sandoz.com with your details, i.e. address, product with batch details, required number of leaflets.

The updated PILs for each strength are available via the Electronic Medicines Compendium (eMC).

Apixaban Sandoz 2.5 mg film-coated tablets - Patient Information Leaflet (PIL) - (emc) | 13807

Apixaban Sandoz 5 mg film-coated tablets - Patient Information Leaflet (PIL) - (emc) | 13806

Advice for Healthcare Professionals to Provide to Patients:

Patients should continue to take Apixaban as prescribed by their healthcare professional. The quality of the tablets is not impacted by the missing label information. If patients have questions about these updates, they should speak to their pharmacist, nurse, or doctor.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Additional information:

For all medical information enquiries and information on this product, please email mi.uk@sandoz.com, or telephone +44 1276 698101.

For stock control enquiries please email sales.sandoz-gb@sandoz.com, or telephone +44 1276 698020.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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