Medicines & Healthcare products Regulatory Agency

# MEDICINES NOTIFICATION

## CLASS 2 MEDICINES RECALL, EL(26)A/49

## Action within 48 hours

Issued 24 November 2026

## Distribute to Pharmacy/Wholesaler Level Recall

### MEDICINE DETAILS

**Brintellix 5 mg Film-coated tablets**

**(incorrectly packed as Brintellix 10 mg Film-coated tablets)**

PLPI: 20774/2321

Active Ingredient: vortioxetine

GTIN (5 mg tablets): 05 060537 816784

GTIN (10 mg tablets): 05 060537 816791

### MARKETING AUTHORISATION HOLDER

Quadrant Pharmaceuticals Limited (Parallel Import)

### AFFECTED LOT BATCH NUMBERS

| Batch No. | Expiry Date | Pack Size | First Distributed |
|---|---|---|---|
| **2856920/4245Z (MAX 4245Z)** | 08/2029 | 28 film-coated tablets | 07/10/2026 |

## Background

Quadrant Pharmaceuticals Ltd is recalling one batch of Brintellix 5 mg film-coated tablets (mislabelled as 10 mg tablets) due to a labelling error with the product strength impacting an unknown number of units. A number of packs containing Brintellix 5 mg film-coated tablets have been supplied in sealed cartons labelled as Brintellix 10 mg film-coated tablets.

Only the parallel imported packs are impacted by this defect.

**Advice for Healthcare Professionals:**

Check any parallel imported packs of Brintellix 10 mg tablets with the batch number 2856920 and secondary batch number MAX 4245Z. If you are in receipt of these tablets, quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Where possible, patients provided with a parallel imported Brintellix 10 mg pack from this batch should be contacted and told to confirm the strength stated on the tablet blisters matches that on the carton and their prescribed medication.

Should a patient be in possession of a pack with the incorrect medicine, pharmacy teams should exercise their professional judgement to supply the correct medication.

Should a patient prescribed Brintellix 10 mg inadvertently take Brintellix 5 mg, the clinical risk to the patient is possible reduced effectiveness. This can cause a persistence or worsening of depressive symptoms, recurrence of major depressive episodes and, in susceptible patients, potentially serious deterioration in mental health, including the possible emergence or worsening of suicidal ideation or suicidal behaviour. However, 5 mg is an approved minimum daily dose of this product.

**Advice for Patients:**

Quadrant pharmaceuticals have received reports of a carton of Brintellix 10 mg film-coated tablets containing blister strips labelled and containing Brintellix 5 mg film-coated tablets. The 10 mg packs are being recalled as a precautionary measure.

If you were prescribed Brintellix **10 mg** film-coated tablets and received a Quadrant Pharmaceuticals pack with the batch number **2856920/4245Z** and **secondary batch number MAX 4245Z** (see the image below), please contact your pharmacy as soon as possible. Return the pack to your pharmacy along with a copy of this notification.

If you believe you have taken 10 mg tablets from this batch with a lower dose than you require and are currently experiencing persistence or worsening of depressive symptoms, please seek immediate medical advice. Please take your medication with you to your healthcare professional.

If you are unsure or have any questions, please seek advice from your pharmacy or other healthcare professionals involved in your treatment.

Patients who experience adverse reactions or have any questions about the 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 maxearnqa@maxearn.co.uk or telephone 01204 471 269.

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

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU

Telephone +44 (0)20 3080 6574

DMRC@mhra.gov.uk

## IMAGE SHOWING BATCH AND MAX NUMBER LOCATION

