

For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, Strategic Planning and Performance Group & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
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Our Ref: PHC/16/2024
Date: 20th May 2024

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Dear Healthcare Professional,

Cygnus Pharma Ltd

Trazodone Hydrochloride 50mg/5ml Oral Solution

PL49255/0004

Batch No	Expiry Date	Pack Size	First Distributed
AS240145A	03/2027	120 ml	May 2024
AS240146A	03/2027	120 ml	May 2024

Active Pharmaceutical Ingredient: Trazodone hydrochloride

Brief description of the problem

Cygnus Pharma Ltd. have informed MHRA that the European Article Number (EAN) barcode printed on the packs is defective and returns the incorrect information. When

scanned the returned information has not been assigned to any medicinal product. The printed barcode will not be used in the future for any product.

The 2D barcode and Global Trade Item Number (GTIN) which appears on the packs returns the correct information when scanned.

Advice for healthcare professionals

The product quality and safety is not affected by this issue. The 2D barcode contains the correct information. Do not use the product with any automated prescribing or dispensing systems that use the EAN barcode.

The notification is intended to make wholesalers/retailers/pharmacies aware of the barcode discrepancy for the batches specified in the tablet and to confirm that the product quality and safety has not impacted by this discrepancy.

Advice for patients

The product quality and safety are not affected by this issue. Patients should continue to take medicines from these batches as prescribed by your healthcare professional.

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](#).

Further Information

For medical information enquiries please email info@cygnuspharma.co.uk or telephone 01582 809833.

For stock control enquiries please email info@cygnuspharma.co.uk or telephone 01582 809833.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Cathy Harrison', is written on a light yellow rectangular background.

Professor Cathy Harrison
Chief Pharmaceutical Officer