

MEDICINES NOTIFICATION CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 20/05/2024 EL (24)A/16 Our Ref: MDR 260-04/24

Dear Healthcare Professional,

Company Name: Cygnus Pharma Ltd

Product Name Trazodone Hydrochloride 50mg/5ml Oral Solution PL 49255/0004

SNOMED Code: N/A

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

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Medicines & Healthcare products Regulatory Agency

For medical information enquiries please email <u>info@cygnuspharma.co.uk</u> 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. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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