



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 14 March 2022

EL (22)A/13

Our Ref: MDR 250-01/22

Dear Healthcare Professional,

CNX Therapeutics Ltd

Latuda 18.5mg film-coated tablets

PLGB 19635/0003

Batch Number	Expiry Date	Pack Size	First Distributed
0011	31 August 2025	28	Not Yet Distributed
0013	31 December 2025	28	Not Yet Distributed

Latuda 37mg film-coated tablets

PLGB 19635/0004

Batch Number	Expiry Date	Pack Size	First Distributed
0020	30 November 2025	28	Not Yet Distributed
0021	30 November 2025	28	Not Yet Distributed

Latuda 74 mg film-coated tablets

PLGB 19635/0005

Batch Number	Expiry Date	Pack Size	First Distributed
0029	31 December 2025	28	Not Yet Distributed
0030	31 December 2025	28	Not Yet Distributed
0031	31 March 2026	28	Not Yet Distributed

Active Pharmaceutical Ingredient: Lurasidone (as lurasidone hydrochloride)

Brief description of the problem

CNX Therapeutics Ltd. have notified the MHRA that the above listed batches of Latuda film-coated tablets will be released without EAN barcodes on the cartons. The batch numbers and the expiry dates are present and clearly visible on the cartons and on the blisters. Although fully in line with the Marketing Authorisation, the absence of the barcodes may lead to queries as these may sometimes be used for stock control and automated dispensing.

This stock has not yet been distributed, however due to the consideration for stock control and automated dispensing, this notification is being shared in advance of distribution from CNX Therapeutics Ltd to wholesalers and pharmacies. The expected distribution dates for these batches will take place between April 2022 and July 2022.



Advice for healthcare professionals and wholesalers

Wholesalers and healthcare professionals should refer to the batch number and expiry date printed on the carton for stock control and dispensing. The impacted products are within specification and there is no issue with product quality and are not being recalled.

Further Information

For more information and medical information contact: medinfo@cnx-therapeutics.com

For stock control queries please contact: supplychain@cnx-therapeutics.com

Recipients of this Medicines Notification 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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