Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Pharmacy / Wholesaler Level

Date: 26 February 2024 EL (24)A/07 Our Ref: MDR 060-02/24

Dear Healthcare Professional,

Orifarm UK Ltd

Concerta XL 18mg prolonged release tablets PLPI 46927/0226 & 46927/0227

Batch No	Expiry Date	Pack Size	First Distributed
3EE35801	31/01/2026	30 tablets	03/11/2023
3EE35802	31/12/2025	30 tablets	03/11/2023
3EE36101	31/01/2026	30 tablets	09/11/2023
3EE35803	31/12/2025	30 tablets	06/12/2023
3EE36102	31/01/2026	30 tablets	14/12/2023
3FE46100	28/02/2026	30 tablets	02/01/2024
3FE46101	28/02/2026	30 tablets	08/01/2024
3GE51900	28/02/2026	30 tablets	24/01/2024

Concerta XL 36mg prolonged release tablets PLPI 46927/0062 & 46927/0207

Batch No	Expiry Date	Pack Size	First Distributed
3AE07102	28/02/2026	30 tablets	06/11/2023
3DE29500	28/02/2026	30 tablets	09/11/2023
3FE44101	30/09/2025	30 tablets	23/11/2023
3FE44102	31/01/2026	30 tablets	23/11/2023
3AE07103	31/12/2025	30 tablets	07/12/2023
3DE29201	30/09/2025	30 tablets	14/12/2023
3DE29501	31/01/2026	30 tablets	14/12/2023
3FE44103	28/02/2026	30 tablets	18/12/2023
3FE46800	31/03/2026	30 tablets	11/01/2024
3FE46801	31/03/2026	30 tablets	17/01/2024
3EE37002	31/01/2026	30 tablets	17/01/2024

Concerta XL 36mg prolonged release tablets PLPI 46927/0063

Batch No	Expiry Date	Pack Size	First Distributed
3GE50002	28/02/2026	30 tablets	17/01/2024

Active Pharmaceutical Ingredient: Methylphenidate Hydrochloride

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Brief description of the problem
Orifarm UK has informed the MHRA of an error with the Patient Information Leaflet (PIL) packaged within the parallel import packs of the above batches of Concerta XL 18mg and 36mg prolonged release tablets. A section of the product side effects containing the serious side effects has been added to paragraph 3 in error however this should be part of paragraph 4. All other sections of the PIL are unaffected.

Advice for healthcare professionals
Healthcare professionals are advised to inform patients of this discrepancy when dispensing packs from the specified batches.

Advice for patients
Patients do not need to take any action. This issue is about an error in the patient information leaflet that accompanies the above specified batches of Concerta XL18mg and 36mg prolonged release tablets. Some information on the side effects is incorrectly included in paragraph 3 instead of paragraph 4. The quality of the medicine is not affected.

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 and stock control queries please email jacook@Orifarm.com, or telephone 01923 204333.

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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