



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 25 November 2020

EL (20)A/54

Our Ref: MDR 091-11/20

Dear Healthcare Professional,

Kyowa Kirin Limited

Abstral 200 microgram sublingual tablets

PL 16508/0031

Batch Number	Expiry Date	Pack Size	First Distributed
608973601	30 Sep 2021	10	09 Feb 2020
608973602	30 Sep 2021	30	28 June 2020

Active pharmaceutical ingredient: Fentanyl citrate

Brief description of the problem

Kyowa Kirin Limited is recalling the above batches as a precautionary measure, due to the reports of double tablets in a single blister pocket. This is a follow up alert, following the issue of EL (20)A/34. Since this notification, Kyowa Kirin Limited have initiated corrective actions to resolve the issue. Complaint batches 608973601 and 608973602 were manufactured prior to the corrective actions being implemented.

One of the corrective actions involved the vision system, which has undergone re-qualification. X-ray units have been sourced to scan and inspect products for empty blister pockets and double fills. X-ray units have been used to inspect all products manufactured and are now part of the standard packing process prior to cartonning. All future blisters will be 100% checked by X-ray units prior to release to the market.

Advice for healthcare professionals

Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Company contacts for further information

For Stock control enquiries please contact

Karen Murray, Commercial Manager

- Telephone: Mobile: +44 (0) 7712 001288
- E-mail: karen.murray@kyowakirin.com

For Medical information enquiries please contact

- Medical Information Direct Line: + 44 (0)1896 664 000
- E-mail: medinfo@kyowakirin.com



For Quality information please contact
Martin Smith (Responsible Person)

- Telephone: Mobile: +44 7904671807
- E-mail: Martin.Smith@kyowakirin.com

Recipients of this Drug Alert 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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