Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 01 July 2021 EL (21)A/15 Our Ref: MDR 143-06/21

Dear Healthcare Professional,

Kyowa Kirin Limited

Xomolix 2.5 mg/ml solution for injection PL 16508/0036

Batch Number	Expiry Date	Pack Size	First Distributed
1821A	07 2021	10 x 1ml ampoules	19 November 2019
1919	11 2022	10 x 1ml ampoules	15 May 2020

Active Pharmaceutical Ingredient: droperidol

Brief description of the problem
Kyowa Kirin Limited is recalling the above batches as a precautionary measure, due to the reports of glass and cellulose fibre contamination, which was identified during stability and reference sample inspection.

Particulate matter could potentially induce a local inflammatory response, such as injection site reactions, which include pain, irritation, erythema as well as potentially, a granulomatous nodule. In rare cases ulceration could potentially develop if the inflammation is intensive but it would usually be limited to the injection site or the surrounding area.

The possibility of occurrence of generalised hypersensitivity would depend on the nature of particulate matter and in case of glass particles, which can also carry metals utilised in glass manufacture, could be considered negligible. Droperidol is known to cause hypersensitivity reactions; anaphylactic reaction, angioneurotic oedema and hypersensitivity are listed as adverse drug reactions in the current Summary of Product Characteristics. Following a review by Kyowa Kirin Limited of all hypersensitivity cases received, this did not detect any information indicative of the reported hypersensitivity reaction being caused by particulate matter.

Parenteral administration of particulates may potentially lead to embolization in small capillaries but such events have not been reported in association with these products since contamination was identified.

Advice for healthcare professionals

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

Patients who have been recently administered a product from the affected batch should be monitored closely, where possible. Healthcare professionals are advised to report any side effects via the MHRA Yellow Card Scheme

General precautions should be considered as part of the handling for this product. As stated in the Summary of Product Characteristics, section 6.6 Special precautions for disposal and other handling, "*The solution should be inspected visually prior to use. Only clear and colourless solutions free from visible particles should be used."*

Further Information
For Stock control enquiries please contact
Karen Murray, Commercial Manager

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- 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 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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