



# MEDICINES RECALL

## CLASS 3 MEDICINES RECALL

Action Within 5 Days  
Pharmacy/Wholesaler Level Recall

Date: 02 March 2022

EL (22)A/10

Our Ref: MDR 084-02/22

Dear Healthcare Professional,

### Kyowa Kirin Services Ltd.

#### Isotard 60mg XL Tablets

PL 16508/0022

Batch Number	Expiry Date	Pack Size	First Distributed
1706875	Nov 2022	28 Tablets	29 Sep 2020

Active Pharmaceutical Ingredient: Isosorbide-5-mononitrate

#### Brief description of the problem

Kyowa Kirin Services Ltd. are recalling the above batch of Isotard 60mg XL Tablets as a precautionary measure due to microfibrils/crystals of the Active Pharmaceutical Ingredient (API) being present on the surface of the tablets as a result of sublimation.

There is no expected impact to product safety and efficacy or risk to patient as the product meets specification and the API microfibrils are considered to only affect tablet appearance. This product is being recalled as a precautionary measure and a replacement batch has recently been released, which is not impacted by this issue.

#### 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.

It should be noted that the microfibrils/crystal issue has no impact on patient or product safety and efficacy.

#### Further Information

For more information please contact:

Customer Services for stock control enquiries:  
Karen Murray - [karen.murray@kyowakirin.com](mailto:karen.murray@kyowakirin.com);  
+44 (0) 7712 001288 (Mobile)

Quality enquiries  
Martin Smith - [martin.smith@kyowakirin.com](mailto:martin.smith@kyowakirin.com)  
+44 (0)7904 671 807 (Mobile)

or for Medical Information enquiries: [medinfo@kyowakirin.com](mailto:medinfo@kyowakirin.com)



For Adverse Event reporting: [medinfo@kyowakirin.com](mailto:medinfo@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

**Defective Medicines Report Centre**  
**10 South Colonnade**  
**Canary Wharf**  
**London**  
**E14 4PU**  
**Telephone +44 (0)20 3080 6574**