

## DRUG ALERT

### CLASS 3 MEDICINES RECALL

Action Within 5 Days

### Pharmacy and Wholesaler Level Recall

Dear Healthcare Professional

**Kyowa Kirin Services Ltd.**

**PL 16508/0022**

**Isotard 60mg XL Tablets**

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:  
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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

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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**TO ALL CHEMISTS, DOCTORS ON THE LISTS**

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2<sup>nd</sup> March 2022

Pharmaceutical website: <http://www.hscbusiness.hscni.net>