Department of Health
An Roinn Sláinte
Männystrie O Poustie
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For Action: Assistant Director Integrated Care, Head of Pharmacy and Medicines Management, HSC Board & BSO
Heads of Pharmacy and Medicines Management of HSC Trusts
Regulation Quality Improvement Authority

From: Chief Pharmaceutical Officer
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Our Ref: PHC-32-2021
Date: 18 November 2021

MEDICINES RECALL

CLASS 2 MEDICINES RECALL
Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Dear Healthcare Professional

SANTEN Oy (trading as Santen UK Limited)

IKERVIS 1 mg/mL eye drops, emulsion EU/1/15/990/001

Batch Number	Expiry Date	Pack Size	First Distributed
8K38Q	03/2022	30 x 0.3ml	26 Sep 2019
4L41F	09/2022	30 x 0.3ml	15 Nov 2019
8L28C	11/2022	30 x 0.3ml	17 Sep 2020

VERKAZIA 1 mg/mL eye drops, emulsion EU/1/15/990/002

Batch Number	Expiry Date	Pack Size	First Distributed
1L14P	05/2022	120 x 0.3ml	29 Jan 2021
4L40H	09/2022	120 x 0.3ml	06 May 2021
6L04J	10/2022	120 x 0.3ml	02 Jul 2021

Parallel Distributors

Orifarm A/S

IKERVIS 1 mg/mL eye drops, emulsion EU/1/15/990/001

Batch Number	Parallel Distributor's Batch Number	Expiry Date	Pack Size	First Distributed
6L03F	6L03F	10/2022	30 x 0.3ml	9th December 2020

Active Pharmaceutical Ingredient: ciclosporin

Brief description of the problem
SANTEN Oy (trading as Santen UK Limited) are recalling the above batches of products as a precautionary measure due to detection of particles/crystals of the active pharmaceutical ingredient ciclosporin. These particles have been detected following microscopic evaluation during stability monitoring.

Following the completion of their investigations SANTEN Oy are recalling the above batches additional to those recalled on 15 September 2021 (Reference PHC-24-2021).

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.

The presence of particles may cause ocular irritation, eye pain and foreign body sensation. Whilst the Marketing Authorisation Holder have not received any reports of adverse reactions being caused by the presence of particles in the above batches, healthcare professionals should advise patients to report any suspected adverse reactions via the MHRA Yellow Card scheme.

Further Information

Santen UK Limited
For more information, please contact +44 (0)1727 615 110 or email enquiries@santen.co.uk

For medical information queries, please contact 0345 075 4863 or email medinfo@santen.co.uk

For supply queries, please contact AAH Customer services at 0344 561 8899

Orifarm A/S
For all enquiries please contact:

Paul Tobin (Responsible Person) on 07583577513 or email at paul.tobin@orifarm.com

Steven Cross (UK Parallel Import Sales Manager) on 07498975920 or email at steven.cross@orifarm.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.

Yours sincerely

Mrs Cathy Harrison
Chief Pharmaceutical Officer