



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 19 Jan 2022

EL (22)A/01

Our Ref: MDR 268-08/21

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
4N46E	05/2023	30 x 0.3ml	March 2021

Active Pharmaceutical Ingredient: ciclosporin

Brief description of the problem

SANTEN Oy (trading as Santen UK Limited) are recalling the above batch 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 new investigations, SANTEN Oy are recalling the above batch additional to those recalled on 15 September 2021 (Reference [EL \(21\)A/22](#)) and 18 November 2021 (Reference [EL \(21\)A/30](#)).

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.

The presence of particles may cause ocular irritation, eye pain and foreign body sensation. The Marketing Authorisation Holder is investigating reports of adverse reactions but these have not been confirmed to be caused by the presence of particles in the above batch. 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

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.



Medicines & Healthcare products
Regulatory Agency



Yours faithfully

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