



MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 15 Sep 2021

EL (21)A/22

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
1L49S	05/2022	30 X 0.3ML	09 October 2019
1N80G	02/2023	30 X 0.3ML	08 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. The company's root cause investigation is ongoing.

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

For more information, please contact Santen UK Limited, Salisbury Hall, St Albans, AL2 1BU, UK at +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

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