



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy and Wholesale Level Recall

Date: 7th June 2016

EL (16)A/07

Our Ref: MDR 116-05/16

Dear Healthcare Professional,

Santen UK Ltd

Ikervis 1 mg/ml eye drops, emulsion (30 single dose containers) EU/1/15/990/001
(ciclosporin)

Batch Number	Expiry Date	Pack Size	First Distributed
9D65E	October 2018	30 x 0.3 ml	21/01/2016
9D65K	October 2018	30 x 0.3 ml	24/02/2016

Santen UK Ltd is recalling batch 9D65E & 9D65K of Ikervis (ciclosporin) 1 mg/ml eye drops emulsion, as micro particles of the active ingredient were found in stability test samples stored at 25 °C/60% RH for 6 months.

Pharmacists and wholesalers are asked to return any remaining stock from these batches to their local AAH depot. All other batches of Ikervis are unaffected by this issue and alternative batches are available for the fulfilment of prescriptions. Patients who are using and have used Ikervis 1 mg/ml eye drops batch 9D65E and 9D65K do not need to return products to the pharmacy because no urgent safety issues have been identified.

Further Information

For Medical Information, please contact telephone number 0345 075 4863 or email medinfo@santen.co.uk.

For enquiries regarding returns please contact AAH Limited, telephone number 0844 5618899, and for stock queries, please call 01727 884523.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. Local area teams are asked to forward this to ophthalmologists, relevant clinics, general practitioners and community pharmacists for information.

Yours faithfully

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