

Date: <XX Month YYYY>

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

IKERVIS 1mg/ml ciclosporin eye drops, emulsion: Interim Supply of Australian Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Santen UK Ltd is currently experiencing supply disruption with IKERVIS 1mg/ml ciclosporin eye drops, emulsion in the UK.

To ensure continuity in supply, Santen has obtained approval from the MHRA to supply Australian product (batch number 6X45E, batch size 12,212 units, expiry May 2029 / batch number 6X28E, batch size 12576 units, expiry April 2029.) which is expected to be on the UK market from 1st October to 31st December 2026.

Please note the following:

- This product is considered licensed for the treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes in the UK.
- The product from Australia has the same formulation as the UK product
- The product from Australia is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are no major differences between the Australian and UK product information. The Australian pack is not supplied with a physical Australian leaflet. The leaflet is provided electronically in Australia. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- Please refer to the UK approved PIL supplied with the Australian packs.
- For additional copies of the leaflet, please refer to <https://www.medicines.org.uk/emc/files/pil.6937.pdf>
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Ikervis and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Please find images of imported Australian packs below. There are a few labelling differences in comparison to standard UK packs. The key differences are that the Australian packs don't contain a list of excipients and distributor details and logo (Seqirus) are mentioned on the pack.

Santen UK Limited. Registered office: Salisbury Hall, St Albans, AL2 1BU. VAT number: GB 209484690.
Company registration number: 09194443

Date of preparation: September 2026

NP-IKERVI-UK-0102

Front Panel	PRESCRIPTION ONLY MEDICINE KEEP OUT OF REACH OF CHILDREN ikervis[®] Ciclosporin 1 mg/mL Eye drops, Emulsion For ocular use only 30 x 0.3 mL single-use ampoules  Aust R 319502 	
Back Panel	Composition: 1 mL of emulsion contains 1 mg ciclosporin. Remove contact lenses before use. Contains no antimicrobial preservative. For single use only. Store below 25°C. Do not freeze. Protect from light. Discard opened single-use ampoules and any remaining contents immediately after use. Keep unopened ampoules in foil pouch to protect from light and avoid evaporation.	
Side Panel	See Consumer Medicine Information for further information. Affix dispensing label here Distributed by: Seqirus (Australia) Pty Ltd Melbourne, Victoria Australia www.seqirus.com.au ikervis is a trademark of Santen SAS.  4 987084 309167	
Top panel	ikervis[®] Ciclosporin 1 mg/mL Eye drops, Emulsion For ocular use only 30 x 0.3 mL single-use ampoules  	

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Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name

Company contact point

If you have any questions about this letter or require more information about Ikervis, please contact Santen Medical Information on medinfo@santen.co.uk or telephone 0345 075 4863 (UK).

Yours faithfully,



Neil Parkin
General Manager
Santen UK

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