



# MEDICINES RECALL

## CLASS 2 MEDICINES RECALL

Action Within 48 Hours  
Pharmacy/Wholesaler Level Recall

Date: 20 September 2022

EL (22)A/40

Our Ref: MDR 050-09/22

Dear Healthcare Professional,

### Novartis Pharmaceuticals UK

#### Sandimmun Oral Solution

PL 00101/0124

Batch Number	Expiry Date	Pack Size	First Distributed
ADP326002	November 2024	50 ml	06/05/2022

Active Pharmaceutical Ingredient: ciclosporin

#### Brief description of the problem

Novartis Pharmaceuticals UK are recalling the above batch due to the presence of crystals in the solution. The crystals have been identified as the active substance (ciclosporin). The presence of crystals has been observed in some finished product packs marketed in other countries that share the same master batch as the UK batch above. Therefore, this UK batch is recalled as a precautionary measure. Novartis Pharmaceuticals UK have confirmed no other batches of the product are impacted.



#### 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.

#### Advice for patients

- Patients should not stop taking Sandimmun Oral Solution without speaking to your doctor or other healthcare professionals, as stopping your treatment may increase the risk of your transplanted organ being rejected.
- The Marketing Authorisation Holder in the UK has not received any product complaints or adverse reactions related to the issue above. However, if you feel unwell whilst taking medicines from this batch then please seek urgent medical attention. Adverse reactions should also be reported via the MHRA [Yellow Card scheme](#).
- If you have any questions about your Sandimmun Oral Solution or observe crystallised particles in the solution, talk to your pharmacist, transplant team or other healthcare professionals for advice.



# Medicines & Healthcare products Regulatory Agency

## **Further Information**

For more information, medical or supply enquiries, please contact 01276 698370, or email [medinfo.uk@novartis.com](mailto:medinfo.uk@novartis.com)

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.

Yours faithfully

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