

MEDICINES NOTIFICATION

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Dear Healthcare Professional,

Novartis Pharmaceuticals UK

Sandimmun Oral Solution

PL 00101/0124

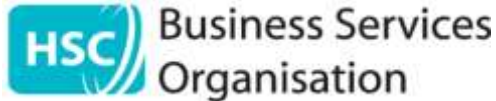
Batch Number	Expiry Date	Pack Size	First Distributed
ADP326002	November 2024	50 ml	06/05/2022

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.

Further Information

For more information, medical or supply enquiries, please contact 01276 698370, or email medinfo.uk@novartis.com

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.