



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

### Caution in Use Pharmacy/Wholesaler Level

Date: 2 December 2024

EL (24)A/59

Our Ref: DMRC-33616486

Dear Healthcare Professional,

## Rosemont Pharmaceuticals Limited

**Mycophenolate Mofetil 1g / 5ml Oral Suspension**

**PLGB 00427/0272**

**SNOMED Code:** 42314611000001100

Batch No	Expiry Date	Pack Size	First Distributed
MYC23001	May 2025	175ml	May 2024
MYC24001	Jun 2025	175ml	May 2024
MYC24002	Jun 2025	175ml	May 2024
MYC24003	Jun 2025	175ml	Jun 2024
MYC24004	Jun 2025	175ml	Jun 2024
MYC24005	Jul 2025	175ml	Jun 2024
MYC24006	Jul 2025	175ml	Jun 2024
MYC24007	Aug 2025	175ml	Sep 2024
MYC24008	Dec 2025	175ml	Not yet distributed

Active Pharmaceutical Ingredient: mycophenolate mofetil

### Brief description of the problem

Rosemont Pharmaceuticals Limited has informed the MHRA that the Press-In-Bottle-Adaptor (PIBA) supplied with the batches listed above may cause the medicine to leak when attempting to withdraw a dose. Further to this, in rare instances, the seal on the PIBA can get damaged and small pieces of plastic may break off.

### Advice for healthcare professional

Healthcare professionals should continue to prescribe the product, the batches listed are **not** being recalled. The PIBA is an aid to dispensing and the product can be administered accurately using the syringe without the PIBA.

Specific 'Advice for patients' is included in this alert for the safe and accurate administering the product. Please provide these instructions to patients when dispensing the product.

The specific instructions in the Patient Information Leaflet (PIL) for cleaning the syringe between administration of doses should continue unchanged.



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## **Advice for patients**

If you have received one of the affected batches in the table, it is important to continue to take your medicine as prescribed by your healthcare professional. Stopping this medication suddenly can make you ill. This product is not being recalled and the following instructions below allow for the continued safe use of the product

The PIBA is the small plastic part included in the package with your medication. It is designed to fit tightly in the neck of the bottle to reduce mess when drawing up doses.

### Bottles already in use

If you have already opened a bottle of the product, leave the PIBA in the bottle and continue to use as directed in the Patient Information Leaflet (PIL) that comes with your medicine. Removing the PIBA will increase the risk of damaging the plastic.

### New bottles not yet opened

The PIBA helps with drawing up the correct dose of medicine but it not necessary to get an accurate dose. The product can be drawn up accurately using the syringe without the PIBA. Please follow the instructions below to get the right amount directly from the medicine bottle:

- Discard the PIBA provided.
- Shake the bottle well, immediately prior to use.
- Remove the cap by pressing it down and turning anticlockwise.
- Keeping the bottle standing upright, insert the syringe supplied into the bottle ensuring the tip of the syringe goes below the level of the liquid.
- Fill the syringe with a small amount of medicine by pulling the piston up whilst maintaining the tip of the syringe below the level of the liquid, then push the piston down to remove any possible bubbles whilst keeping some medicine in the syringe.
- Pull the piston upward to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor.
- Remove the syringe from the bottle.
- Close the bottle with the plastic screw cap.
- Empty the contents of the syringe directly into your mouth. Do not mix the medicine with any other liquid when you swallow it.
- Immediately after use, wash the syringe as per the instructions in the PIL, using water only and leaving it to dry in the air.

If you have any concerns about the medicine you are using, please contact your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

## **Further Information**

For medical information enquiries please contact [pharmacovigilance@rosemontpharma.com](mailto:pharmacovigilance@rosemontpharma.com), or telephone 0113 244 1400.

For stock control enquiries please contact [customerservices@rosemontpharma.com](mailto:customerservices@rosemontpharma.com), or telephone 0113 244 1999.

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.



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Yours faithfully

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