



**31-Jul-2025**

**DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION**

**Rapamune® (sirolimus) 1 mg/ml, 60 ml oral solution - restricted use of medicinal product beyond the expiration date of syringe adapter (PLGB 00057/1614)**

Dear Healthcare Professional,

PFIZER LIMITED in agreement with the MHRA, would like to inform you of the following:

**SUMMARY**

Misalignment between the expiration date on the syringe adapter and the drug product has been observed for lot CVXZF. The syringe adapter component (Lot: 1104247) expiry date is 9 February 2027 and precedes the expiry date of lot CVXZF 28 February 2027.

**Due to that fact, medicinal product lot CVXZF should not be used after 9 February 2027.**

**FURTHER INFORMATION ON THE SAFETY CONCERN AND THE RECOMMENDATIONS**

Pfizer confirms that the syringe adapter remains usable until 9 February 2027 without any product quality or patient safety risk.

**BACKGROUND INFORMATION**

RAPAMUNE is an mTOR inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in adult patients at low to moderate immunological risk receiving a renal transplant. It is also indicated for the treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function. The full Product Information for RAPAMUNE can be found at: [Rapamune 1mg/ml Oral Solution - Summary of Product Characteristics \(SmPC\) - \(emc\) | 8116](#)

The product is supplied in an amber glass bottle (60mL), with a syringe adapter for fitting into the neck of the bottle, patient information leaflet, disposable oral syringes in a sealed bag for daily dosing, and a carrying case.

For medicinal product lot CVXZF, the expiration date on the syringe adapter component precedes the expiration date of the oral solution. The syringe adapter component (Lot: 1104247) expiry date is 9<sup>th</sup> February 2027. Therefore, the component and whole drug product should not be used after this time. Rapamune oral solution medicinal product lot CVXZF can be safely used by 9<sup>th</sup> February 2027 according to the use restrictions provided in the Product Information.

Pfizer confirms that the discovered issue does not impact other medicinal product lots, other than this indicated in this letter.

Refer to Table 1 below for a list of impacted batches of Rapamune Oral Solution in the UK.

**Table 1.** List of batches that have been distributed in the UK

Country	Batch number
United Kingdom	CVXZF

**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

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.

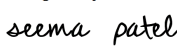
Please continue to report any suspect adverse drug reactions to [www.pfizersafetyreporting.com](http://www.pfizersafetyreporting.com)

**COMPANY CONTACT POINT**

Alternatively, suspected adverse reaction may also be reported to the Marketing Authorisation Holder using the details provided below. If you have further questions or require additional information, please contact:

Company	Product name	Email	Phone
Pfizer Ltd	Rapamune Oral Solution	medical.information@pfizer.com	01304 616161

Yours sincerely,

Signed by:  
  
 224F8EB693AD465...

Seema Patel  
 Specialty Care Medical Director  
 Pfizer UK