

<Date>

Rapamune (sirolimus) 1 mg/mL oral solution: restricted use of affected lots due to misalignment between expiry dates on the syringe adapter and oral solution

Dear Healthcare Professional,

Pfizer in agreement with the European Medicines Agency and <National Competent Authority> would like to inform you of the following:

Summary

- **The expiry date of the syringe adapter included in the following lots of Rapamune 1 mg/mL oral solution precedes the expiry date of the oral solution.**

Table 1. List of affected lot numbers in circulation

Lot Number	Expiry Date	Market
CVSDB	31/03/2027	Portugal, Spain, Ireland
CVVWC	31/03/2027	Netherlands, France, Belgium
CVVWK	28/02/2027	Germany, Austria
CWNVF	28/02/2027	Iceland
CVVWH	28/02/2027	Denmark

- **The expiry date of the syringe adapter component (Lot: 1104247) is 9 February 2027.**
- **Affected lots of Rapamune should not be used after 9 February 2027.**

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 recommended that Rapamune be used initially in combination with ciclosporin microemulsion and corticosteroids for 2 to 3 months. Rapamune may be continued as maintenance therapy with corticosteroids only if ciclosporin microemulsion can be progressively discontinued (see sections 4.2 and 5.1 of the summary of product characteristics, SmPC).

Rapamune is indicated for the treatment of patients with sporadic lymphangioleiomyomatosis with moderate lung disease or declining lung function (see sections 4.2 and 5.1 of the SmPC).

Each pack of Rapamune contains one bottle (amber glass) containing 60 mL of Rapamune solution, one syringe adapter, 30 dosing syringes (amber plastic) and one syringe carry case.

For the lots of Rapmune oral solution listed in Table 1. List of affected lot numbers in circulation, the expiry date on the syringe adapter precedes the expiry date of the oral solution. The syringe adapter component (Lot: 1104247) has an expiry date of 9 February 2027. Therefore, the syringe adapter and whole drug product should not be used after 9 February 2027.

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

Call for reporting

Healthcare professionals are asked to report any suspected adverse drug reactions in accordance with the national spontaneous reporting system and include batch/Lot number if available. <include the details (e.g. name, postal address, phone number, website address) on how to access the national spontaneous reporting system>.

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	Rapamune oral solution 1 mg/ml, 60 ml
Marketing authorisation holder(s)	Pfizer Europe MA EEIG
Safety concern and purpose of the communication	Expiration date on the syringe adapter precedes the expiration of the medicine
DHPC recipients	Pulmonologists, transplantologists, other healthcare professionals such as specialized primary care physicians and pharmacists. The target group should be further defined at national level, in agreement with the respective national competent authority.
Member States where the DHPC will be distributed	European Union Member States: Ireland, Portugal, Spain, Germany, Netherland, Austria, Iceland, Denmark, France, Belgium
Timetable	
DHPC and communication plan (in English) agreed by CHMP	12 August 2025
Submission of translated DHPCs to the national competent authorities for review	CHMP agreement date + 1 week
Agreement of translations by national competent authorities	CHMP agreement date + 2 weeks
Dissemination of DHPC	CHMP agreement date + 4 weeks