

Date: 14-06-2026

Direct Healthcare Professional Communication

Avrolem® (Everolimus): Important Information to Minimize Unintended Ingestion of the Moisture Absorber Contained in the Blister Packs

Dear Healthcare Professional,

Tabuk Pharmaceuticals, in agreement with the Saudi Food and Drug Authority (SFDA), would like to inform you of important information regarding Avrolem® (Everolimus).

Summary:

- Avrolem® blister packs contain a moisture absorber intended to maintain product quality and stability. Healthcare professionals are advised to reinforce patient counseling and ensure patients are appropriately guided to consume only the intended medicinal tablets contained within the blister pack.
- As part of ongoing product-use enhancement activities, interim warning stickers on the outer packaging are being implemented in coordination with SFDA.

Further Information:

The Avrolem® blister pack includes a moisture absorber **marked with a red warning sign**. The moisture absorber consists of inert material intended solely for humidity control and should not be consumed. Appropriate patient counseling and patient awareness regarding the presence of the moisture absorber within the blister pack are important to support correct product administration and minimize the potential for unintended ingestion of the desiccant instead of the intended medicinal tablet.

The overall benefit–risk profile of Avrolem® remains favorable and unchanged.

Healthcare professionals are encouraged to:

- Reinforce patient counseling during dispensing and administration.
- Advise patients to consume only the intended medicinal tablets.
- Inform patients regarding the presence of the moisture absorber within the blister pack (marked with a red warning sign).

As part of ongoing risk minimization activities:

- **Avrolem® outer packaging will include warning stickers** to enhance patient awareness and support appropriate product use.
- As a long-term measure, packaging enhancement activities are ongoing in coordination with the SFDA to further support safe and appropriate product use.

The information in this communication has been agreed with the Saudi Food and Drug Authority (SFDA).

Call for reporting for adverse reactions:

Adverse reactions or product-use issues related to Avrolem® should be reported to the following contacts:

Tabuk Pharmaceuticals, Pharmacovigilance:

Email: pv.info@tabukpharmaceuticals.com

Tel: +966114774946

SFDA, National Pharmacovigilance Center:

Unified Contact Center: 19999

Email: npc.drug@sfda.gov.sa

Website: <https://ade.sfda.gov.sa>

QR code for e-Reporting:



Yours sincerely,

Saad Alharthi (Qualified Person for Pharmacovigilance)

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