Envarsus® – prolonged-release tacrolimus tablets

Educational materials for the healthcare professional (doctor or pharmacist).
Please read the full Summary of Product Characteristics before prescribing **Envarsus®.**

Warning: Risk of confusion between **Envarsus®** and other oral tacrolimus medicines. Other formulations of oral tacrolimus are not equivalent or freely interchangeable. During the prescription, preparation and dispensing processes confusion can lead to underdosing, overdose and/or toxicity. ***Envarsus®*** *must always be administered* ***once daily in the morning.***

1. What are Envarsus® prolonged-release tablets and what are they used for?
Envarsus® tablets contain prolonged-release tacrolimus, an immunosuppressant that inhibits T-lymphocyte activation. **Envarsus®** can be used for prophylaxis or treatment of kidney or liver transplant rejection.

2. Why does Envarsus® need to be prescribed by brand?
To avoid medication errors, prescribing and dispensing must be made by the brand name, **Envarsus®**.

3. What are the clinical risks associated with under- and overdosing?
Tacrolimus is a drug with a narrow therapeutic index, and even minor differences in blood levels have the potential to cause transplant rejection or adverse reactions.

Inadvertent, unintentional or unsupervised substitution of immediate- or prolonged-release tacrolimus have been observed. This has led to serious adverse reactions, including graft rejection or other adverse reactions which could be a consequence of either under- or overexposure to tacrolimus.

Patients should be maintained on a single formulation of tacrolimus with the corresponding dosing regimen; if alterations in formulation or regimen are clinically indicated, this should only take place under the close supervision of the clinical specialist, as close monitoring of tacrolimus levels is required.

Underdosing can lead to biopsy confirmed acute rejection of transplanted organs. Overdosing can cause toxicity due to overexposure to tacrolimus. Experience with overdosage is limited. Several cases of accidental overdose have been reported; symptoms have included tremor, headache, nausea and vomiting, infections, urticaria, lethargy, increased blood urea nitrogen and elevated serum creatinine concentrations, and increase in alanine aminotransferase (ALT) levels.

4. How can prescribing errors be avoided?
- Prescribers must familiarise themselves with the **Envarsus®** Summary of Product Characteristics (SmPC) when prescribing this medicine to a patient.
- Whether using electronic or paper-based prescriptions ensure that you clearly specify the brand name **Envarsus®**.
- **Envarsus®** is a **prolonged-release** tablet formulation and has to be taken **once daily in the morning.**
- If you have any doubt check the actual pack of the medicine if available, check the medical record and discuss with the pharmacist if necessary to ensure you are prescribing the correct medication for your particular patient. If a clinical decision is made to change the tacrolimus brand of a patient, close monitoring by a specialist is required.

5. How can pharmacy dispensing errors be avoided?

- Pharmacists must familiarise themselves with the **Envarsus®** SmPC.
- Be aware when reading prescriptions that there are other forms of oral tacrolimus.
- Double check that the intended medication is **Envarsus®** tablets.
- In case of any doubt, consult with the treating physician.
- Familiarise yourself with the different cartons, labels and tablet colours to select the correct medication.
- Store **Envarsus®** in a different place to other forms of oral tacrolimus.

6. What is the role of the patient card?

Patients taking **Envarsus®** will be provided with a patient card to raise awareness of the need to take the same brand of oral tacrolimus.

7. How can you report suspected adverse reactions?

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions to HPRA Pharmacovigilance, Earlsfort Terrace, IRL, Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

Please also report ***any adverse event or reaction, expected and unexpected, serious or not,*** which you think may be related to **Envarsus®** as soon as possible to:

Chiesi Limited
Email: pv.uk@chiesi.com
Tel: +44 161 488 5555
Fax: +44 161 488 5566

8. Additional information

Further copies of this healthcare professional educational material and the patient alert card are available from Chiesi Limited.

Copies can be requested from:

Tel: +44 161 488 5555
Email: info@chiesi.uk.com

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