Position Statement

Prescribing of Oral Tacrolimus

Recommendation:

Dailiport modified release oral capsules are recommended for all patients who are newly prescribed modified release tacrolimus for transplant rejection – **RAG status RED for new patients**

Please note:

Dailiport modified release capsules are not bioequivalent to Adoport immediate release capsules and do not replace Adoport capsules.

Existing patients using Advagraf modified release capsules will remain on Advagraf and are not routinely switched to Dailiport. If a prescriber considers that switching a patient to a different brand of oral tacrolimus would be of benefit, the change requires careful supervision and therapeutic monitoring by an appropriate specialist.

Background

Tacrolimus is an immunosuppressant drug that may be given orally to prevent or treat organ transplant rejection. Tacrolimus has a narrow therapeutic index, and even minor differences in blood levels have the potential to cause graft rejection reactions or toxicity.

In June 2012, following reports of graft rejections and toxicity resulting from switching between products, the MHRA issued a Drug Safety Update recommending that all oral tacrolimus products should be prescribed and dispensed by brand name only:

> The growing number of oral tacrolimus products available on the market increases the potential for inadvertent switching between products, which has been associated with reports of toxicity and graft rejection. Therefore, to ensure maintenance of therapeutic response when a patient is stabilised on a particular brand, oral tacrolimus products should be prescribed and dispensed by brand name only. If a prescriber considers that switching a patient to a different brand of oral tacrolimus would be of benefit, the change requires careful supervision and therapeutic monitoring by an appropriate specialist [1]

Dailiport Modified Release Capsules

The European Medicines Agency granted a marketing authorisation for Dailiport modified release capsules for:

- Prophylaxis of transplant rejection in adult kidney or liver allograft recipients.
- Treatment of allograft rejection resistant to treatment with other immunosuppressive medicinal products in adult patients.

The EMA concluded that bioequivalence studies demonstrated that the pharmacokinetic profile of Dailiport is similar to the pharmacokinetic profile of Advagraf. [2]

Prescribing of oral tacrolimus in Lancashire and South Cumbria

Renal transplant patients in Lancashire and South Cumbria are prescribed their immunosuppressant therapy from Lancashire Teaching Hospitals and this is funded by NHS England. This specialist centre has no plans at present to switch patients from Advagraf to Dailiport. Prescribing still exists outside of specialist centres. In the year to June 2023, the primary care spend on oral tacrolimus across Lancashire and South Cumbria was approximately £250,000.

Bibliography

[1] Medicines and Healthcare products Regulatory Agency, "Oral tacrolimus products: prescribe and dispense by brand name only, to minimise the risk of inadvertent switching between products, which has been associated with reports of toxicity and graft rejection," December 2014. [Online]. Available: https://www.gov.uk/drug-safety-update/oral-tacrolimus-products-prescribe-and-dispense-by-brand-name-only-to-minimise-the-risk-of-inadvertent-switching-between-products-which-has-been-associated-with-reports-of-toxicity-and-graft-rejection?UNLID=1462430802. [Accessed September 2023].

[2] College Ter Beoordeling Van Geneessmiddelen, "Public Assessment Report Dailiport prolonged release hard capsules," 2019 December 2019. [Online]. Available: https://mri.cts-mrp.eu/portal/v1/odata/Document(9cd2667d-da29-eb11-80eb-0050569c593a)/Download. [Accessed September 2023].

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Version Control

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