Prescribing of Tacrolimus Products by the Edinburgh Transplant Unit

Tacrolimus is used for the prophylaxis of graft rejection following solid organ transplantation.

The MHRA advises that tacrolimus should be prescribed and dispensed by brand name to minimise the risk of toxicity and graft rejection.

To date, Prograf® has been the first line immediate-release tacrolimus formulation of choice in Edinburgh for transplant patients. However, after a careful review of the evidence and upon consideration of cost-effectiveness it has been agreed by NHS Lothian that all newly transplanted patients will be prescribed Adoport® rather than Prograf® by the transplant teams in Edinburgh. This change commenced the 1st of August.

Any patients currently prescribed Prograf® will be reviewed and a decision made by the specialist team if it is appropriate to switch to Adoport® when patients next attend the outpatient clinic. If patients are to be switched, letters will be sent to the GP, community pharmacy and the patient to inform them of the switch.

There are no plans currently to switch patients who are prescribed the once daily formulation Advagraf®.

The above switch only relates to patients under the care of the transplant unit in Edinburgh. Patients attending the transplant unit in Glasgow should continue to be prescribed the brand recommended by the Glasgow Unit.

- Please ensure that Tacrolimus products are prescribed by brand name in line with the brand recommended by the specialist Transplant Units.

Always Prescribe Insulin by Brand Name

Several insulin products have, or are due to, become available as biosimilar products eg Insulin Lispro. Biosimilar insulins are not interchangeable due to differences in pen devices and must be prescribed by brand name.

The preferred brand of Insulin Lispro in Forth Valley is Humalog®. However, Insulin Lispro is also available as a biosimilar product made by Sanofi called Insulin Lispro Sanofi®. To ensure the patient receives the correct insulin on each occasion it should be prescribed by the appropriate brand name. This is crucial as the Humalog® cartridge does not fit into the Sanofi pen device and vice versa.

The current generic entry on EMIS does not specify any brand and we are aware that some generic prescribing of Insulin Lispro exists. This can result in patients potentially receiving the wrong insulin brand (Sanofi biosimilar where Humalog® was intended). Ongoing EMIS drug dictionary entries updates will add an entry for the Sanofi product however this is not in place at the moment.

- The Diabetes Team have advised that ALL insulin prescriptions (for any type of insulin) should be prescribed by brand name.
- Humalog® is the preferred brand of Insulin Lispro in FV
- This should be prescribed by brand name as per recommendation letters from the Diabetes Team.
- Any current generic prescribing of Insulin Lispro should be updated to brand name prescribing. Patients should be contacted to confirm which brand they are currently using and EMIS records should be updated accordingly.

Key Points of interest:
- Change of preferred tacrolimus brand in Edinburgh unit. Ensure correct brand name prescribing.
- Ensure insulins prescribed by brand name.
- Updated prescribing restrictions for Esmya®
- Stop Smoking access options for patients.
- New vitamin D guidance:
  - Updated product choices
  - Ensure appropriate length of treatment
- Lothian CF Shared Care Agreements

Best wishes for the Festive Season
Drug Safety Updates
Selected highlights from recent Drug Safety Update Bulletins from the MHRA (https://www.gov.uk/drug-safety-update)
Prescribers are encouraged to subscribe directly to the Drug Safety Updates Bulletin which is only available by email. www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/email-signup

Recent Drug Safety Updates you may have missed......

Updated Prescribing Advice Ulipristal (Esmya®) for the Treatment of Uterine Fibroids

New measures to ensure the safe prescribing of Esmya® and to minimise the risk of serious liver damage have been introduced following an EU review.

Prior to prescribing, women should be advised of the rare risk of liver damage with Esmya® and the need for ongoing liver monitoring. They should be advised of the signs and symptoms of liver damage e.g. tiredness, yellowing of the skin, nausea and vomiting, darkening of the urine.

Restrictions to Prescribing
• Esmya® treatment should only be initiated and supervised by a physician experienced in the diagnosis and treatment of uterine fibroids
• Esmya® is contraindicated in women with underlying liver disorders
• Esmya® is only indicated for –
  ◊ One treatment course of pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age
  ◊ The intermittent treatment of moderate to severe symptoms of uterine fibroids in women of reproductive age who are unsuitable for surgery

Monitoring Requirements
Liver function monitoring is required –
• Before initiation of each treatment course. Do not prescribe if baseline ALT or AST levels are 2x the upper limit of normal (ULN)
• Monthly during the first two treatment courses. For further treatment courses before each new course and when clinically indicated.
• 2-4 weeks after the end of each treatment course
If ALT/AST levels increase to ≥3x ULN - stop Esmya®, closely monitor patient and consider referral to hepatology specialist.

For further information on the updated safety advice refer to Summary of Product Characteristics for Esmya® and the August 2018 Drug Safety Update.

• Ensure patients are only prescribed Esmya® in line with new prescribing restrictions.
• Careful monitoring of LFTs is required

Stop Smoking—options for patients

Patients who wish to access support to stop smoking can access this from the Stop Smoking Team or from any Community Pharmacy.

Some of the Stop Smoking Advisers now supply NRT products directly to patients in clinics however as this is not available in all locations some patients may receive a letter requesting supplies of NRT. These patients can still be referred to their community pharmacy for a supply. The pharmacy will register the patient to allow supply of NRT and submission of the minimum dataset information.
Updated Vitamin D Guidance

NHS Forth Valley Guidance - ‘Investigation and Treatment of Vitamin D deficiency in Adults’ has recently been reviewed and updated.

The guidance highlights the following areas –

- Treatment algorithm
- When to treat based on vitamin D levels
- Usual recommended products, doses and duration lengths for treatment initiation and maintenance.

It is recommended that once the initial vitamin D deficiency has been corrected, patients requiring long-term maintenance of vitamin D levels should be advised to purchase an OTC supplement (containing 400-800 IU of vitamin D) and also be provided with lifestyle advice.

Product choice has been updated. The current products of choice for treatment of Vitamin D deficiency are:

Fultium® D3 20,000 IU capsules, Desunin® 4000 IU tablets or Invita® D3 25,000 IU oral solution

ScriptSwitch® has been updated to reflect the current products of choice and an updated FV EMIS Formulary will be issued to reflect the updated formulary choices.

Prescribers should:
- Refer to the updated Vitamin D guidance to ensure the appropriate treatment and management of patients who are considered vitamin D deficient
- To ensure appropriate length of treatment prescribers may wish to add a stop date on the prescription.

Lothian Shared Care Agreements for Cystic Fibrosis Patients

NHS Lothian have Shared Care Agreements (SCAs) in place for a number of medicines used in adult patients with Cystic Fibrosis (CF) (aztreonam, colistimethate and dornase alfa) and have asked that GPs in NHS Forth Valley are aware of these to ensure that any FV patients managed by the Lothian tertiary services can receive these drugs via their GP to allow ongoing treatment.

The tertiary service will provide information requesting the ongoing prescribing and where to find the SCA for information. Monitoring and review of these treatments is undertaken by the CF centre so the GP is only responsible for ongoing supply and reporting any issues back to the centre.

The Primary Care Prescribing Group and Area Drug and Therapeutics Committee have reviewed the SCAs and are satisfied that they are suitable to support FV GPs in prescribing these medicines.

The SCAs are available on the following website:
http://www.ljf.scot.nhs.uk/SharedCareofMedicines/Pages/default.aspx

Contact Information:

General Primary Care Prescribing Advice:
Contact your Primary Care Pharmacist; or alternatively
Primary Care Prescribing Support Team on 01324 566722
Email: FV-UHB.prescribingsupports@nhs.net

For Advice Related to Management of Controlled Drugs:
Kirsty Peacock, Inspection Officer for Controlled Drugs,
NHS Forth Valley, Forth Valley Royal Hospital Tel: 01324-566743
Email: kirsty.peacock@nhs.net