LOTHIAN PRESCRIBING BULLETIN

Supporting prescribing excellence - informing colleagues in primary and secondary care

NHS Lothian

In this issue ...

Issue No. 97 **May 2019**

Gluten free fallout

Regulations for the prescribing of gluten free products in England have changed significantly as a result of a review by the Department of Health and Social Care (DHSC). The aim of the review was to reduce variation in practice between the Clinical Commissioning Groups and generate efficiencies. Gluten free products are now widely available to purchase in supermarkets, often at a similar cost to equivalent gluten containing products. Following consultation, DHSC made the decision to restrict prescribing to only bread and bread mixes. The Advisory Committee on Borderline Substances (ACBS) has now confirmed a list of approved products, which is published on the English Drug Tariff website.

The Scottish Government has no plan to review the existing Scottish Gluten Free Food Service, where community pharmacists can supply an accepted quantity of gluten free products for patients registered with a Scottish GP practice with confirmed coeliac disease or dermatitis herpetiformis. Boards may have different products available on their formularies, although they can only include products listed under Part 16 of the Scottish Drug Tariff.

As a result of these changes in England some manufacturers are starting to reduce the number of products available on prescription. In light of these changes the availability of products to prescribe may be less than those available to purchase in supermarkets.

In NHS Lothian the first product affected in the Lothian Joint Formulary is Nairn's Porridge Oats, which has now been removed. An alternative product has been added in its place. See the LJF section for full information.

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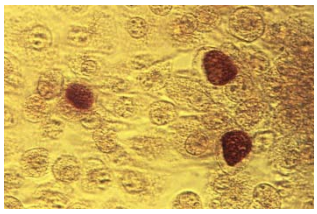
Chlamydia treatment changes



The LJF choices for *Chlamydia trachomatis* treatment have changed. This change reflects the 2015 UK National Guidelines BASHH for the management of genital tract infection with *Chlamydia trachomatis*. Please refer to the LJF 5.0(d) for full information.

First choice:	**doxycycline** 100mg **twice daily** for 7 days
Second choice:	**azithromycin** 1g (4 x 250mg) as a single dose followed by 500mg daily for 2 days. Note that the treatment dose of azithromycin has changed
Pregnancy:	**doxycycline** is contraindicated in pregnancy. There are limited data for use of azithromycin use in pregnancy but clinical experience suggests it is safe and effective

The community pharmacy chlamydia treatment service has been updated to reflect this change, with the introduction of a revised service specification and new PGD for doxycycline. There is a requirement for the community pharmacy to ensure appropriate counselling. All updated service documentation can be found here.

Drug safety updates

Two recent MHRA Drug Safety Updates highlighted areas of interest. The articles below are from the December 2018 and February 2019 issues. Information has been added to the Summary of Product Characteristics and Patient Information Leaflets for these medicines. Any suspected reactions should be reported via the Yellow Card Scheme.

Carbimazole – new concerns

There are two new concerns associated with the use of carbimazole.

Women of child-bearing potential should use effective contraception whilst taking carbimazole due to an increased risk of congenital malformations. The risk is higher in the first trimester and at daily doses of 15mg or more. Carbimazole must only be considered during pregnancy following a detailed, patient-centred assessment of the risks and benefits of treatment by a specialist. If the benefits outweigh the risks then it should be prescribed at the lowest effective dose without the requirement for additional thyroid hormones. Close maternal, foetal and neonatal monitoring is recommended. Patients should be advised to see their doctor promptly if they may be pregnant or are planning a pregnancy.

If acute pancreatitis occurs during treatment with carbimazole, treatment should be discontinued immediately and an alternative prescribed. This is a very rare side-effect and re-exposure of carbimazole may result in life-threatening acute pancreatitis with a decreased onset time, hence it is recommended never to restart carbimazole.

Fournier's gangrene and SGLT2 inhibitors

There have been post-marketing reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum) associated with the use of sodium-glucose co-transporter 2 (SGLT2) inhibitors. Fournier's gangrene is a rare but potentially life-threatening infection. If suspected it is recommended to stop the SGLT2 inhibitor and urgently start appropriate treatment of the infection. Secondary complications are urogenital infection or perineal abscess. Patients should be advised to seek urgent medical attention if they experience fever or malaise with genital/perineal swelling, severe pain, tenderness, or erythema.

Risk of hypoglycaemia with hepatitis C treatment

Studies have shown that some patients with diabetes have experienced hypoglycaemia when started on direct-acting antiviral (DAA) therapy for hepatitis C. It appears that achieving a sustained virological response to the DAAs is associated with improvements in glycaemic control. Adjustments to diabetic medication may be required in up to 30% of patients.

- Rapid reduction in viral load during DAA therapy may lead to improved glucose metabolism, resulting in hypoglycaemia
- Inform the patient of the risk of hypoglycaemia and to be vigilant for changes in glucose tolerance.

Emollients – risk of burns extended

The MHRA has now clarified that the risk of severe and fatal burns has been extended to all paraffin-based emollients regardless of paraffin content. The data suggests there is also a risk for paraffin-free emollients. Although emollients are not flammable, they act as an accelerant, increasing the speed of ignition and intensity of the fire when fabric with residue dried on is ignited. Points to remember:

- When prescribing, recommending, dispensing, selling or applying emollient products, remind patients of risk of smoking or being near naked flames
- Washing clothing or fabric at high temperature may reduce emollient build-up but not totally remove it
- There is no risk-free choice since all emollients regardless of paraffin concentration carry a fire risk.

Conditional Marketing Authorisation - and a study shows no survival benefit

A conditional marketing authorisation (CMA) can be granted by the European Medicines Agency (EMA)[1] for new medicines. These are given for medicines that address unmet medical needs of patients. They are granted when the benefit of immediate availability outweighs the risk of less comprehensive data being available. The manufacturer of the medicine has to agree to provide the additional clinical data to the EMA to confirm that the benefit-risk balance is positive. A CMA is valid for one year and can be renewed annually. The CMA could be converted to a standard marketing authorisation, once the comprehensive data has been obtained.

An example
Olaratumab (Lartuvo®) is indicated for advanced soft tissue sarcoma, it is given in combination with doxorubicin. It was granted a CMA based on data from a randomised phase II trial, which had shown an overall survival benefit. Continued approval was linked to confirmation of this benefit from the ANNOUNCE trial.[2]

In the MHRA Drug Safety Update in February 2019, it was highlighted that a letter has been sent to all prescribers noting that **no new patients are to be prescribed olaratumab** due to the ANNOUNCE study showing no clinical benefit. The phase 3 study (ANNOUNCE) did not show benefit in terms of survival and progress-free survival compared with doxorubicin alone. The manufacturer is working with medicine regulators to ascertain the next steps for olaratumab. **This medicine is no longer considered to be approved for use in NHS Lothian. No new patients should be started on treatment.**

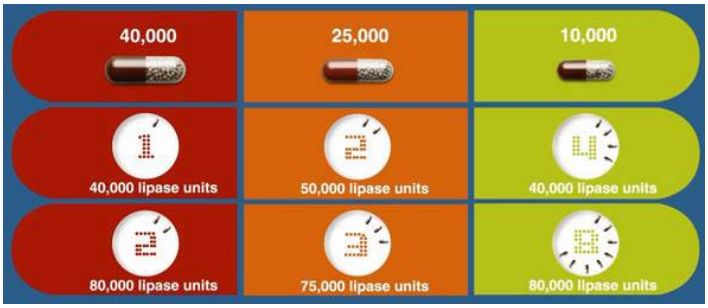
References:
1. Conditional marketing authorisation. European Medicines Agency. www.ema.europa.eu/en/human-regulatory/marketing-authorisation/conditional-marketing-authorisation
2. Drug Safety Update volume 12, issue 7: February 2019: 4. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779462/DSU-PDF-Feb-2019.pdf

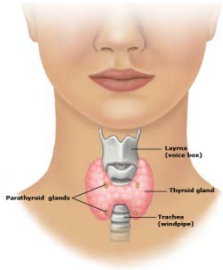
Discontinuation of Creon 40,000 unit capsules

Mylan Pharmaceuticals will be discontinuing Creon 40,000 unit capsules from June 2019. In the meantime there may be intermittent supply.

Please see the switching guide. It may be appropriate to convert to 25,000 unit capsules for patients with a high capsule burden to reduce the number of capsules required.

If you have any questions then please get in touch with the specialist team looking after your patient.





Liothyronine: a reminder

The role of liothyronine (T3) in the management of hypothyroid disease remains controversial. An article was included in a previous Lothian Prescribing Bulletin Issue 85 May 2017, highlighting the main issues. Recently, health boards received a letter from the Scottish Government asking to confirm that:

- *there is holistic and safe review of patients prescribed T3*
- *clinicians initiate and continue T3 where it is safe and clinically appropriate to do so, as agreed with a consultant who specialises in endocrinology.*

Liothyronine is not included in the Lothian Joint Formulary. Levothyroxine (T4) monotherapy is first line in the treatment of primary hypothyroidism as it remains the safest and most effective treatment for most patients. The use of combination T4 and T3 should only be initiated by an endocrinologist.

The endocrine team accept referrals from primary care for the consideration of T3 therapy. Patients are counselled very carefully about the pros and cons of therapy and if a decision is made to initiate treatment it is done on a trial basis. Treatment is only continued if there is evidence of benefit to the patient and may be transferred to primary care for continuation. Any changes should be made in consultation with a specialist and T3 treatment should not be stopped suddenly.

Clearing the hurdles of taking medicines abroad

When booking a holiday, medication regulations are not at the forefront of patients' minds. Many are unaware of the risks and restrictions around foreign travel with medication. High profile cases have caught international attention and highlighted dangers of taking medications abroad. There are many information resources available for travellers.[1]

Medication should remain in original packaging and with its original dispensing label for personal use.

Many medicines, including opioids, psychotropics, stimulants and controlled drugs, require additional documentation and permits. Also, as a result of airport security measures there are restrictions on the volume and number of liquid items allowed in hand luggage. It may not be clear to passengers that this includes medications, and have serious implications for those who require liquid preparations, injections and inhalers. Consideration should also be given to OTC products and medical devices such as needles.

Four hurdles

The first hurdle is getting the medication out of the UK, the UK Civil Aviation Authority Guidance highlights important information with regards to medical conditions and flying. The second hurdle is entering the foreign country. Travellers need to be aware that the legal status of medicines differ in other countries, therefore it is essential to check with the country's embassy before travelling. The third hurdle is to retain any documentation and original packaging required for entering the country when exiting. The fourth hurdle is re-entering the UK. Medication prescribed in the UK should pose no problem, however bringing medication obtained abroad back into the UK may not be permitted.

Patients travelling with controlled drugs must check the Home Office website for current regulations and documentation requirements.[2]

Top tips for patients travelling abroad with medicines

- ✓ Plan well ahead, including any travel vaccines, and order your medicines in plenty of time
- ✓ Obtain appropriate documentation from your prescriber
- ✓ Check legal and airline requirements that apply to the movement of medicines into and out of all destination countries (may require contacting appropriate embassy)
- ✓ Carry your medicines in original packaging in your hand luggage
- ✓ Ensure that you have sufficient quantity for the duration of your trip and that you store your medicines appropriately
- ✓ Ensure comprehensive holiday insurance, declaring any medical conditions and medicines.

References:

1. Fit for Travel. Health Protection Scotland, NHS National Services Scotland. https://www.fitfortravel.nhs.uk/advice/general-travel-health-advice/travelling-with-medicines
2. Travelling with medicine containing a controlled drug. Home Office. https://www.gov.uk/travelling-controlled-drugs

Thanks to Julie Williams and Eleanor England, Pre-registration Pharmacists, for contributing this article.

Prescribing Indicators 2019/20

The NHS Lothian Prescribing Indicators (PIs) for 2019/20 have been agreed by the General Practice Prescribing Committee (GPPC). A full list of the PIs is available from the LJF website in 'Prescribing Bulletins' as a downloadable supplement.

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