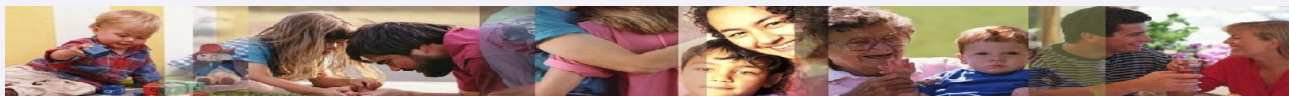


NEWSLETTER



In This Issue

- ⊕ LAMAs and cardiovascular risk
- ⊕ Reminder: Tacrolimus — prescribe by brand
- ⊕ Alternative to bimatoprost 0.03% multidose?
- ⊕ Clarification on recently published Cow's Milk Allergy Newsletter supplement
- ⊕ New NICE guidance
- ⊕ Managed Entry decisions

LAMAs AND CARDIOVASCULAR RISK

The MHRA issued a Drug Safety Update (<https://www.gov.uk/drug-safety-update>) on tiotropium following the TIOSPIR trial which found that there was no significant difference in mortality for tiotropium delivered via Respimat compared with Handihaler. The previous caution on use of tiotropium via the Respimat now applies to the Handihaler delivery system as well. These cautions were issued because clinical trials of tiotropium excluded patients with certain cardiac conditions such as recent myocardial infarction, unstable cardiac arrhythmia and heart failure NYHA Class III or IV.



Therefore when using tiotropium to treat chronic obstructive pulmonary disease (COPD):

- Take the risk of cardiovascular side effects into account for patients with conditions such as those above that may be affected by the anticholinergic action of tiotropium
- Tell these patients to report any worsening of cardiac symptoms after starting tiotropium
- Review the treatment of all patients already taking tiotropium to ensure that it remains appropriate for them; regularly review treatment of patients at high risk of cardiovascular events.

It is worth noting that there are 3 other long-acting anti-muscarinic (LAMA) agents currently available: aclidinium (Duaklir Genuair[®], Eklira Genuair[®]), glycopyrronium (Seebri Breezhaler[®], Ultibro Breezhaler[®]) and umeclidinium (Anoro Ellipta[®], Incruse[®]). The SPC for each of these drugs details caution in relation to patients who have suffered a recent myocardial infarction, unstable angina/heart disease, or arrhythmias as these patients were also excluded from the clinical trials.

Action

Ensure that all patients who are using a LAMA have regular reviews and ensure that a cardiovascular history is taken into consideration during these respiratory reviews.

REMINDER: TACROLIMUS — PRESCRIBE BY BRAND

Oral tacrolimus is one of the drugs for which generic prescribing is not appropriate, yet prescribing data indicates that **nearly 400 prescriptions were issued for generic tacrolimus capsules in Northern Ireland in the last six months.**

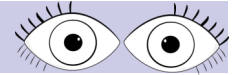


The MHRA advised in 2012 that oral tacrolimus should be prescribed and dispensed by brand: 'The growing number of oral tacrolimus products available on the market increases the potential for inadvertent switching between products, which has been associated with reports of toxicity and graft rejection. 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.'

Action

- Prescribe all oral tacrolimus products by brand name only (for liquid 'specials' the manufacturer should be specified on the prescription).
- Search for patients who have been prescribed this drug generically. Establish the appropriate brand (clarification with discharge note, patient and/or pharmacy) and update repeat prescribing record in the practice to ensure future prescribing is for specific brand.
- For further information refer to guidance on items that are unsuitable for generic prescribing http://www.hscboard.hscni.net/medicinesmanagement/Prescribing%20Guidance/index.html#P-1_0

ALTERNATIVE TO BIMATOPROST 0.03% MULTIDOSE?



Bimatoprost ophthalmic solution 0.03% (Lumigan[®]) multidose eye drops are to be discontinued from 30th April 2015. Bimatoprost 0.01% multidose eyedrops will continue to be available. Bimatoprost 0.01% is equivalent to the 0.03% formulation in intraocular pressure lowering efficacy. The 0.01% formulation also demonstrates an improved tolerability profile in terms of hyperaemia severity, ocular adverse events and subsequent patient discontinuation.

Action

- Bimatoprost 0.01% multidose eye drops should be used instead of bimatoprost 0.03% multidose eyedrops.
- Single use bimatoprost 0.03% unit dose drops (30 x 0.4ml) should be reserved for patients who have a sensitivity to preservatives.

Clarification on recently published Cow's Milk Allergy Newsletter supplement

The article mentioned that some infants e.g. those with severe or multiple allergies or those with IgE cow's milk allergy (CMA) will require an amino acid formula (AAF) first line.

- Whilst it is correct to say that infants with either suspected severe IgE or severe non-IgE CMA will require to be commenced on an AAF first line, infants with mild to moderate IgE CMA *can* be commenced on an extensively hydrolysed formula (EHF).
- Some infants may initially be appropriately started on an EHF. However they may then go on to develop more severe signs or symptoms or even to have suspected multiple food protein allergies, when a change to an AAF may be needed.
- Less commonly, exclusively breast fed infants may also develop CMA and details on how to manage these patients can be found on page 4.5 of HSCB Infant Feeding Guidelines
http://www.hscboard.hscni.net/medicinesmanagement/Prescribing%20Guidance/045%20Infant_Feeding_Guidelines_Feb%202014.pdf



Name Change: Nutramigen AA[®] is changing its name to Nutramigen Puramino[®]. There is no difference between the two products. GP clinical systems will be updated so that when Nutramigen AA[®] is ordered the product will be highlighted as being changed to Nutramigen Puramino[®]. Supplies of the new product will begin to appear in local wholesalers when current supplies of Nutramigen AA[®] are exhausted.

NEW NICE GUIDANCE

[NICE Guidelines NG2](#) - Bladder cancer: diagnosis and management of bladder cancer.

MANAGED ENTRY DECISIONS

The following medicines were considered in March as part of the Northern Ireland Managed Entry process. **For details of the outcomes please refer to the Managed Entry section of the Northern Ireland Formulary website:** <http://niformulary.hscni.net/ManagedEntry/MEDecisions/Pages/default.aspx>

Primary and Secondary Care

- Apixaban (Eliquis[®])

Secondary Care

- Nab-paclitaxel (Abraxane[®])
- Ofatumumab (Arzerra[®])
- Aztreonam lysine (Cayston[®])
- Vedolizumab (Entyvio[®])
- Fosfomycin (Fomicyt[®])
- Obinutuzumab (Gazyvaro[®])

- Peginterferon beta 1a (Plegridy[®])
- Sipuleucel-T (Provenge[®])
- Ustekinumab (Stelara[®])
- Rifaximin (Targaxan[®])
- Topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine
- Collagenase clostridium histolyticum (Xiapex[®])
- Omalizumab (Xolair[®])
- Idelalisib (Zydelig[®])

This newsletter has been produced for GPs and Pharmacists by the Regional Pharmacy and Medicines Management Team. If you have any queries or require further information on the contents of this newsletter, please contact one of the Medicines Management pharmacists in your local HSCB office.

Belfast Office: 028 9536 3926
South Eastern Office: 028 9147 5133
Southern Office: 028 9536 2009
Northern Office: 028 9536 2835
Western Office: 0300 555 0115

References

- 1) MHRA. Tiotropium delivered via Respimat compared with Handihaler: no significant difference in mortality in TIOSPIR trial. Drug Safety update, Feb 2015.
- 2) HSCB. Items unsuitable for generic prescribing.
- 3) MHRA. 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. Drug Safety Update, June 2012.
- 4) HSCB. Medicines Safety Matters, August 2012.
- 5) BSO. Drug Tariff, March 2015.
- 6) Cardiff and Vale UHB newsletter, April 2015. Discontinuation of bimatoprost 0.03% multidose eye drops
- 7) Personal communication with the Regional Glaucoma Service Northern Ireland, 24/4/2015.

Every effort has been made to ensure that the information included in this newsletter is correct at the time of publication. This newsletter is not to be used for commercial purposes.