

The purpose of the Medicines Management newsletter is to deliver succinct, evidence-based advice and information on primary care prescribing issues. Aimed at busy prescribers wanting to know key messages from the many publications in the previous month.

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1. What's in the news

Articles relevant to primary care

For full access to the DTB articles login via Open Athens those without accounts: <https://openathens.nice.org.uk/>

DTB December 2014, Volume 52, Number 12

1. Changes in reporting ADRs in children

Medicines and Healthcare products Regulatory Agency (MHRA) has updated and simplified its guidance for healthcare professionals reporting suspected adverse drug reactions (ADRs) in children to its Yellow Card Scheme (<http://www.mhra.gov.uk/yellowcard>) now in line with that for adults.

2. Brimonidine for erythema caused by rosacea

Brimonidine gel is used for the symptomatic treatment of facial erythema of rosacea in adults. Rosacea is a poorly understood long-term chronic relapsing condition, with no cure and the treatments are to control symptoms. DTB commented that brimonidine effect on erythema has not been compared with other interventions for rosacea and based on such limited evidence it is difficult to assess its place in therapy.

JAPC classified this as RED (for specialist use only) indicated for the symptomatic treatment of facial erythema of rosacea in adults where quality of life is severely impaired by the rosacea, and alternative treatments are not suitable

Deleted products from MIMS for December

Amphotril (amphotericin), Cepton Medicated Lotion (chlorhexidine), Hyalase (hyaluronidase), Interpose, PKU Start, Repevax (dTaP/IPV vaccine), Travasept 100 (chlorhexidine/cetrimide), Woundcare dressing pack and Xelma

2. Drug Safety Update relating to primary care prescribing

(For more information see [Drug Safety Update : MHRA](#)) Volume 8, Issue 5, December 2014

Ivabradine (Procoralan) in the symptomatic treatment of angina: risk of cardiac side effects—new advice to minimise

Ivabradine may be associated with the risks of bradycardia, atrial fibrillation, and other cardiovascular risks

New advice for healthcare professionals:

When using ivabradine to treat the symptoms of chronic angina:

- only start ivabradine if the resting heart rate is at least 70 beats per minute
- do not prescribe ivabradine with other medicines that cause bradycardia, such as verapamil, diltiazem, or strong CYP3A4 inhibitors
- monitor patients regularly for atrial fibrillation. If atrial fibrillation occurs, carefully reconsider whether the benefits of continuing ivabradine treatment outweigh the risks
- consider stopping ivabradine if there is no or only limited symptom improvement after 3 months

The MHRA also remind healthcare professionals of the following:

- ivabradine is indicated to treat symptoms of chronic angina in patients unable to tolerate or with a contraindication to beta-blockers. It can also be used in combination with beta-blockers in patients for whom an optimal beta-blocker dose is not enough
- the recommended starting dose is 5 mg twice daily
- do not exceed the maximum maintenance dose of 7.5 mg twice daily
- Down-titrate the dose if resting heart rate decreases persistently below 50 beats per minute or if the patient experiences symptoms of bradycardia. The dose can be down-titrated to 2.5 mg twice daily if necessary
- stop ivabradine treatment if the resting heart rate remains below 50 beats per minute or symptoms of bradycardia persist

In Derbyshire GPs may prescribe ivabradine after specialist/consultant initiation after a period of 4 weeks of optimised treatment.

3. Local News and GP queries

GP query

The medicines management teams from time to time are asked for their advice on use vaccines following a break down in the cold chain caused by fridge failure.

Answer

The medicines management teams' response to this is for practice staff to quarantine the affected vaccines and contact the manufacturers for specific advice. The decision on whether the vaccine is unsuitable to use is taken by a GP at the practice noting its use will be "off-label".

Useful resources include:

1. Leaflet explanation guide for parents from [Public Health England](#) for 'off label' use when the vaccine is still considered to be safe and effective.
2. Public Health England has also produced a [Vaccine incident guidance: responding to vaccine errors](#) which is more detailed report. This includes useful flow charts GP practices may wish to share with their immunisation teams summarising actions to take in the event of errors (see algorithm for managing a cold chain breach where vaccines have not been administered to patients on page 13).

Procedure following a cold chain incident

- Quarantine all vaccines affected and maintain in the cold chain (another fridge) label (Do not use).
- Inform NHS England Screening and Immunisation Coordinator (SIC) who will advise next steps, and the need to call the manufactures will be discussed at this point.
- If the practice requires to call the manufactures list each vaccine and record advice given, this information to be discussed with SIC
- **Do not discard** any vaccines until all relevant information has been gathered and discussed between the practice and the SIC/ Area Team.
- Complete an incident form and send to SIC.
- Report the incident on the ImmForm website www.immform.dh.gov.uk

It is strongly recommended that a data logger is insitu in each validated vaccine fridge. Information attached. They can also be purchased via Hillside medical supplies or LEC product link below

http://www.medicalrefrigeration.co.uk/product_info.php?products_id=1436&osCsId=ab898b32c5db9ac095ee02cf8abcbdf1

GP query 2

I have been asked to issue an urgent prescription for the brand Keppra on the instructions of a consultant neurologist for a patient that has been seen privately. Please advise as I have read somewhere that branded prescribing for anti-epileptics is advised.

Answer

Advice relating to this specific drug is covered in our formulary [Chapter 4](#) see Section 4.8.1, this is in line with recent [MHRA advice](#). Keppra (levetiracetam) falls into the lower category of risk and deemed unnecessary to prescribe as brand. The variation in therapeutic index, solubility and absorption are unlikely to affect epileptic control. Unless there is a clinical reason, requests for Keppra should be prescribed as its generic levetiracetam.

This particular query related to a patient that had been seen privately who then opted back into the NHS. Patients are free to move between private and NHS providers. However private patients prescribed non-Derbyshire formulary items should be counselled to expect NHS Derbyshire formulary drugs if moving into the NHS. Derbyshire has a prescribing specification that forms part of contract with our providers. The Derbyshire [Prescribing Specification](#) is a useful document that outlines our CCG commissioning intentions with providers and is part of a contract. The specification also outlines expectations as to time lines for patients requesting prescriptions.

Local news

DHcFT wish to raise awareness of the key findings from an audit on Dementia completed by the trust. They have asked that CCGs raise awareness amongst their GPs of;

- the low presentation rates amongst ethnic minorities
- to be more pro-active in seeking out these patients
- Reminded always to send a summary list of medications along with referrals.

4. QiPP

Advice for prescribers on the risk of the misuse of pregabalin and gabapentin

[PHE and NHSE](#) has published an expert group's advice for prescribers on the risk of misuse of pregabalin and gabapentin, and suggestions for a balanced and rational use of these medicines. Prescribers are warned to balance the benefits of prescribing and the risk that these drugs can lead to dependence and may be misused or diverted. Less harmful, alternative drugs can often be first-line treatments for the indicated conditions for which pregabalin and gabapentin are now used, and may be tried preferentially in higher risk settings or in patients who may be more likely to be harmed by the drugs.

Where tapered withdrawal is necessary the paper cites the summary of product characteristics that both drugs can be discontinued over one week. However a more gradual dose taper allows observation of emergent symptoms that may have been controlled by the drug.

- Pregabalin: reduce the daily dose at a maximum of 50-100mg/week.
- Gabapentin: reduce the daily dose at a maximum rate of 300mg every four days.

Pregabalin is structurally related to gabapentin and has a similar pharmacologically action and adverse event profile. Locally we have advised that pregabalin is only recommended in patients after a trial of gabapentin for patients that have gained benefit from gabapentin but not tolerated it.

Self-management for patients with chronic obstructive pulmonary disease - The Cochrane Library

Self-management interventions in patients with COPD were associated with improved health-related quality of life as measured by the St George's Respiratory Questionnaire, a reduction in respiratory-related hospital admissions and improvement in dyspnoea as measured by the modified Medical Research Council Scale. Over 1 year of follow-up, the NNT* to prevent respiratory-related hospital admissions ranged from 8 (high baseline risk) to 20 (low baseline risk). No statistically significant differences were found in other outcome parameters (all-cause hospitalisation, mortality, exercise capacity).

Zwerink M et al. Self management for patients with chronic obstructive pulmonary disease. Cochrane Reviews, 2014, Issue 3. Art. No.: CD002990.DOI: 10.1002/14651858. CD002990.pub3. This review contains 29 studies involving 3688 participants

Flu vaccination- reminder

Practices are reminded that different brands of flu vaccine have differing licenses dependant on age and therefore need to familiarise themselves with these differences to help inform correct ordering and administration to the right patient group.

Useful resources include the [green book](#) and the [electronic Medicines Compendium \(eMC\)](#)

For the attention of practices

The NHSBSA Prescription Services request that CCGs make practices aware that where Fluenz Tetra vaccine nasal suspension or Influenza vaccine (live attenuated) nasal suspension have been centrally procured for the practice through Public Health England, they should not make a claim under personal administration arrangements to the NHSBSA on form FP34P/D Appendix.

An FP34P/D appendix should only be submitted for payment where the vaccine has been purchased by the practice specifically for personal administration

5. **NICE Evidence summaries: New medicines and unlicensed/off-label** relating to primary care prescribing

New medicines

Erectile dysfunction: Alprostadil cream

Summary-In 2 randomised controlled trials (RCTs) alprostadil 300 microgram cream statistically significantly improved erectile function and intercourse ability compared with placebo but the average absolute benefit was modest and only 31%–40% of men (depending on outcome considered) obtained a clinically relevant response. Most reported adverse events were mild to moderate, transient and localised. There are no long term safety data for the use of alprostadil cream and its excipients in treating erectile dysfunction and there are no published comparisons with other drug treatments.

This is consistent with JAPCs decision that classified alprostadil as BROWN after specialist initiation as per SLS criteria; usually 2nd line to a PDE-5 inhibitors. Generic sildenafil is the preferred cost effective treatment option to treat erectile dysfunction

Unlicensed/ off-label reviews

n/a to primary care

6. Useful resources

BMJ	www.thebmj.com
JAMA: The Journal of the American Medical Association	http://jama.ama-assn.org/
The Lancet	www.thelancet.com
The New England Journal of Medicine	http://content.nejm.org/
BMJ, JAMA and NEJM can be accessed in full-text directly through your NHS Athens Account via: National Library for Health: search via My Journals MyAthens: Via National Library for Health Resources or Local Resources. Current Lancet articles are sometimes available with free registration from http://www.thelancet.com/content/register. Print copies of The Lancet are available at DCGH library.	www.library.nhs.uk or www.athens.ac.uk
If you have not already registered for an NHS Athens Account, please register at: NB: It is recommended that you register on a Trust (NHS) PC for speedy confirmation of your username a password. Once registered, your account can be accessed from any computer with online access.	https://register.athensams.net/nhs/nhseng/
UKMI Nathnac NHS evidence Electronic medicines compendium Clinical Knowledge Summaries Medicines Prescribing Centre (Formerly NPC) Medicines for children (patient information leaflets) Drugs in lactation	http://www.ukmi.nhs.uk/ https://www.evidence.nhs.uk/search?om=%5B%7B%22srn%22%3A%5B%22%20ukmi%20%22%5D%7D%5D http://www.nathnac.org/ http://www.evidence.nhs.uk/ http://www.medicines.org.uk/emc/ www.cks.nhs.uk. http://www.nice.org.uk/mpc/ http://www.medicinesforchildren.org.uk/ http://www.midlandsmedicines.nhs.uk/content.asp?section=6&subsection=17&pageldx=1
UK teratology services	http://www.uktis.org/index.html
Vaccine update- Vaccination newsletter for health professionals and immunisation practitioners	https://www.gov.uk/government/organisations/public-health-england/series/vaccine-update