NHS
West Hampshire
Clinical Commissioning Group

Medicines Optimisation news headlines

June/July 2017

Pregabalin

NHS England has withdrawn its previous guidance about Pregabalin (issued in March 2015) and as required by the Court, has issued the following guidance which came into effect on the 17 July 2017:

1. When prescribing pregabalin for the treatment of any condition, you should prescribe in accordance with your normal practice.
2. When dispensing pregabalin for the treatment of any condition, you should dispense in accordance with your normal practice

In effect all pregabalin should be prescribed by the generic name. People who have already been switched to the branded generic Alzain, can remain on this brand.

Prescribers should remain mindful of the following cautions that apply to any prescription for pregabalin:

- It has the potential to cause dependence and be misused.
- It should be used with caution in patients with certain co-morbidities such as diabetes, renal impairment, heart failure and in elderly patients at risk of falls.
- It can have serious adverse effects on the central nervous system which are additive when used with other centrally-acting drugs, particularly opioids.

'Excipient-free' medicines

From time to time queries arise about the excipient content of medicines, such as lactose or gelatin. Unfortunately there isn't a standard resource available to find medicines that are free from particular excipients and in general each medicine has to be researched individually.

There is an advanced search function on the eMC website, where the Summary of Product Characteristics (SPC) documents for some, but not all products, are held. The advanced search allows you to filter by SPC section, allowing a drug name to be searched but an excipient excluded. This will highlight any of the products containing that drug that do not contain a particular excipient.

It is also worth remembering that unless the product information states a quantity for the excipient it could be a very small or trace amount. In a recent enquiry about the sucrose content of a tablet, (as listed as an excipient in the SPC,) it was found that the amount was less than the level at which the manufacturers need to declare a level; i.e. less than 2mg per tablet. To put this in context, a teaspoon of sugar is approximately 4.2g.

Lucozade – reduced sugar content

It is important that any patients with diabetes who use Lucozade for hypoglycaemia are aware that the he sugar content has now been reduced**.** Further information is available from Diabetes UK.

Magnesium hydroxide mixture

The Emis description for this product has changed.

It is now listed as magnesium hydroxide 8% oral suspension.

PPIs and risk of death

A recent newspaper article featured a study that had been published in the BMJ concerning a possible increased risk of death for patients taking PPIs.

It was an **observational** study that listed the following strengths and limitations:

- *National large-scale data from a network of integrated health systems.*
- *Employed a new user design and developed a number of analytical approaches that consistently found a significant association between PPI exposure and risk of death.*
- *Cohort included mostly older white male US veterans, which may limit the generalisability.*
- *Did not include information on the cause of death.*

The original report further expands expand on these last 2 points:

> *"There were significant baseline differences in that cohort participants who were treated with PPI were older and were more likely to have comorbid conditions, including diabetes, hypertension, cardiovascular disease and hyperlipidaemia. Cohort participants treated with PPI were also more likely to have upper GI tract bleeding, ulcer disease, H. pylori infection, Barrett's oesophagus, achalasia, stricture and oesophageal adenocarcinoma."*

No clear causal relationship of an increased risk of death was demonstrated with PPIs. No immediate action is required, but PPI use should be reconsidered as part of a general medicines review and either the dose reduced if possible or deprescribed if no longer clinically indicated.

Denosumab

5 reports of osteonecrosis of the external auditory canal have now been received worldwide, for patients treated with 60 mg denosumab for osteoporosis. The number of cases of osteonecrosis of the external auditory canal is low compared with those of osteonecrosis of the jaw, but the MHRA has issued the following recommendation:

- The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving denosumab who present with ear symptoms including chronic ear infections or in those with suspected cholesteatoma.
- Possible risk factors include steroid use and chemotherapy, with or without local risk factors such as infection or trauma.
- Advise patients to report any ear pain, discharge from the ear, or an ear Infection during denosumab treatment.
- Report cases of osteonecrosis of any bone suspected to be associated with denosumab or any other medicine on a Yellow Card.

Mirvaso

Further advice has been issued by the MHRA regarding Mirvaso (brimonidine gel) for the treatment of rosacea:

- Cases of bradycardia, hypotension (including orthostatic hypotension), and dizziness after application of brimonidine gel have been reported, some of which required hospitalisation.
- Some cases were associated with application of brimonidine gel after laser procedures to the skin, which possibly caused increased absorption of the gel.
- Warn patients not to apply brimonidine gel to irritated or damaged skin, including after laser therapy to the skin.

Full details can be found in the June Safety Update

Catherine McLean
Interface Pharmacist, Medicines Management
catherine.mclean2@nhs.net
023 8062 7466

Dr Emma Harris
Clinical Director, Medicines Management
ejharding@doctors.org.uk