

Medicines

Optimisation news headlines

October 2015

Safety Updates

Mirabegron and Hypertension

Hypertension is a known side effect of mirabegron. However, cases of severe hypertension have now been reported, including hypertensive crisis associated with cardiac and cerebrovascular events (mainly transient ischaemia attack or stroke).

The following [advice](#) has now been published by the MHRA:

- Mirabegron is contraindicated in patients with severe uncontrolled hypertension (systolic blood pressure ≥ 180 mm Hg or diastolic blood pressure ≥ 110 mm Hg, or both)
- Blood pressure should be measured before starting treatment and monitored regularly during treatment, especially in patients with hypertension
- Suspected side effects to mirabegron should be reported on a [Yellow Card](#)

Dabigatran & Creatinine Clearance

Dabigatran dosing should be reduced or even stopped in patients with impaired or fluctuating renal function. Failure to do this increases the risk of severe or even fatal haemorrhage.

As renal impairment may be frequent in patients over 75 years of age, renal function should be assessed by calculating the creatinine clearance (CrCl) from serum creatinine prior to initiation of treatment. It is not enough to use the eGFR value as this can produce an overestimate of renal function on which to base drug dosing decisions, especially in frail elderly patients. A more accurate measurement can be calculated with the Cockcroft and Gault equation that uses age, serum creatinine (in micromol/l) and ideal body weight to obtain CrCl. There are many calculators available to do this but one example is available through Athens:

<http://www.medicinescomplete.com/mc/bnf/current/PHP18586-creatinine-clearance.htm>

Renal function should also be assessed at least once a year and more frequently in clinical situations where it is suspected that the renal function could decline or deteriorate (such as hypovolaemia, dehydration, and concomitant use of certain other medicines).

Anticoagulant Decision Aid

An updated and simplified version of the [anticoagulant decision aid](#) is now available on the CCG website. It is presented as a flowchart and includes information on all four of the novel anticoagulants that are recommended by NICE as an option for stroke prevention in AF.



Focus on Specials

Glyceryl Trinitrate and Diltiazem for Treatment of Chronic Anal Fissure

Between June and August 175 prescriptions requesting unlicensed topical glyceryl trinitrate and diltiazem preparations were dispensed for patients in the West Hampshire CCG area.

There have been two evidence summaries from NICE dealing with these preparations that raised the following points:

- In the case of topical diltiazem 2%, a Cochrane review and 2 additional randomised controlled trials found that the efficacy was not statistically significantly different from topical glyceryl trinitrate, but that limited evidence indicated a reduced frequency of headaches.
- The Association of Coloproctology of Great Britain and Ireland has suggested that the strength of glyceryl trinitrate (0.2% or 0.4%) does not influence the efficacy but increases the incidence of side effects, particularly headache. It is not known whether applying less ointment of the same strength, rather than reducing the strength of ointment applied, might have an effect on the incidence of headache.

Although topical glyceryl trinitrate 2mg/g (0.2%) ointment has a standard list price in the Drug Tariff it does not currently have UK marketing authorisation and its use is therefore unlicensed. Rectogesic® rectal ointment, containing 0.4% glyceryl trinitrate, is a licensed alternative for the treatment of anal fissure that could be suitable for many patients. None of the diltiazem preparations are licensed, but Anoheal®, containing 2% diltiazem, is a registered product that is available on a named patient basis, so providing a consistency of the preparation. Rectogesic® is the first choice product for the treatment of anal fissure, but if the incidence of headache is unacceptable then Anoheal® would be the preferred alternative.

Price comparison for a 1x30g tube (Drug Tariff October 2015)

Glyceryl trinitrate 0.2% ointment; Tariff special.....	£28.06
Rectogesic 0.4% ointment.....	£39.30
Diltiazem 2% cream; Tariff special.....	£71.05
Diltiazem 2% ointment; Tariff special.....	£66.62
Anoheal 2% cream.....	£50.40

Prednisolone 5mg in 5ml oral solution (Prednisolone Dompé)

A new vanilla and honey flavoured solution is available in 5mg single dose units which has a lower acquisition cost than 5mg soluble tablets (£11.41 compared to £17.83 for ten doses). Each pack contains a measuring spoon to enable doses of 3.75 ml, 2.5 ml and 1.25 ml to be administered, (corresponding to 3.75mg, 2.5mg and 1.25mg respectively). All opened units should be discarded once the required dose is removed.

NB: NOTE STRENGTH – other higher strength solutions are also on the market.

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