Medicines Safety Bulletin

Issue 2 – June 2021

North Yorkshire Clinical Commissioning Group

Welcome to the latest edition of our Medicines Safety Bulletin; a newsletter produced by your local CCG Medication Safety Group. Our aim is to highlight to you medication safety concerns that have been raised both locally and nationally, in order to promote and support safer practice.

Chloramphenicol eye drops and their use in children younger than 2 years

Colleagues maybe aware that the summary of product characteristics (SPCs) for chloramphenicol 0.5% eye drops were updated recently to include a contraindication in children under 2 years of age.This was due to the prescence of boron or borates in the formulation, which have been associated with a potential future risk of impaired fertility. Most UK manufacturers of chloramphenicol eye drop preparations have now revised their SPCs and leaflets to include this warning. However, following a review of the available toxicological data and calculation of daily exposure to boron from a typical dosing regimen, the MHRA have issued a Drug Safety Update stating that the balance between the benefits and risks of chloramphenicol eye drops containing borax or boric acid remains positive for children aged 0 to 2 years. They advise that chloramphenicol eye drops can be safely administered to children of any age where antibiotic eye drop treatment is indicated.

The product information for affected chloramphenicol products is being updated to reflect the revised advice and remove restrictions for use in infants – in the meantime we ask healthcare professionals to reassure parents and carers that these products can be safely given to children aged 0 to 2 years as prescribed.

There is no change to the SPC for chloramphenicol 1% eye ointment, as this does not contain boric acid or borates

Pharmacy-only (P) preparations of both chloramphenicol drops and ointment are not licensed for sale or supply to children under 2 'over the counter' and so their licences and leaflets already had this age resctriction included, but for a different reason.

MHRA Drug Safety Update: https://www.gov.uk/drug-safety-update/chloramphenicol-eye-drops-containing-borax-or-boric-acid-buffers-use-in-children-younger-than-2-years

Citalopram oral drops safety update

Following an incident in West Yorkshire, a reminder that citalopram oral drops are not bio-equivalent to tablets. Citalopram oral drops have approximately 25% increased bioavailability compared to tablets. Consequently, doses of tablets correspond to doses of drops as follows:

Tablets	**Solution**	
10mg	8mg	(4 drops)
20mg	16mg	(8 drops)
30mg	24mg	(12 drops)
40mg	32mg	(16 drops)
60mg	48mg	(24 drops)

Further information can be found here: https: //www.medicines.org.uk/emc/product/3349/smpc

Medication errors with rivastigmine patches

In 2010, an MHRA Drug Safety Update for rivastigmine patches reported medication errors which resulted in overdose and hospital admission in some cases. Despite this update, errors involving rivastigmine patches continue to be reported. Errors have occurred at several points in the prescribing, dispensing and administration processes. Multiple patch application is the most commonly reported patient safety incident. The number of manufacturers and different strengths of rivastigmine patches available in the UK may increase the likelihood of errors. Confusion between rivastigmine and rotigotine patches has also occurred, mainly during the dispensing process, but errors during prescribing and administration were also noted.

Suggestions for mitigating the risk of patient safety incidents include: providing clear advice to patients, relatives, carers, and healthcare personnel on safe application of patches; and, documentation of patch applications, using records and dating applied patches, to avoid multiple patch application. Clear instructions on dispensing labels indicating that only one patch should be applied at a time should also be provided. A review of clinical systems and product storage in dispensaries to prevent wrong product or wrong strength errors are also suggested. Further information can be found here:

https://www.sps.nhs.uk/wp-content/uploads/2019/03/UKMI_QA_rivastigmine-patches_Mar21_FINAL.pdf

Reduction in zopiclone dose in patients with hepatic dysfunction and new contraindication

Due to reduced elimination, the zopiclone SPCs now advise a lower dose of 3.75 mg in hepatic dysfunction and contraindicate use in severe hepatic insufficiency, due to risk of encephalopathy. Caution is also advised in patients with depression, with treatment for no longer than 4 weeks. The revised SPC for 'Zimovane' brand can be viewed here:

https: //www.medicines.org.uk/emc/product/2855/smpc

Reminder to use 'MD+CALC' Cockcroft-Gault equation for some drug dose adjustments

In 2019 the MHRA issued advice that creatinine clearance (CrCl) should be used to determine dosage adjustments for certain groups of patients and certain medicines such as direct-acting oral anticoagulants (DOACs). Locally there has been evidence that patients admitted to hospital have not been on the correct dose of DOAC when taking into account their CrCl.

The CCG recommends using the MD+CALC Cockcroft-Gault equation which can be accessed using the link: https://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation (can also be downloaded as an App for mobile devices). This will calculate a modified estimate of CrCl with a range that is based on ideal body weight (IBW) to adjusted body weight (ABW). If the difference crosses over a DOAC dosing threshold, then assess bleeding and thrombosis risk to decide on suitable dose. The inbuilt calculators in the GP clinical systems do not give the ability to view the potential range of CrCl and are therefore less reliable when precise calculation is required.

Further information on prescribing for renal impairment can be found here: https://www.gov.uk/drug-safety-update/prescribing-medicines-in-renal-impairment-using-the-appropriate-estimate-of-renal-function-to-avoid-the-risk-of-adverse-drug-reactions

and here: https://bnf.nice.org.uk/guidance/prescribing-in-renal-impairment.html?UNLID=63244173202161661142

This bulletin has been produced by the North Yorkshire & Vale of York CCG Medicines Management Teams on behalf of the North Yorkshire & York Medicines Safety Group. If you have any queries or feedback relating to the bulletin we can be contacted using the Rxline mail box: nyccg.rxline@nhs.net

We also welcome any suggestions or ideas you may have for future editions.