Medicines Safety Matters

A Newsletter from the Derbyshire and Nottinghamshire CCGs Medicines Safety Officers Network. Issue 5, September 2017

Welcome to our regular edition of Medicines Safety Matters; a newsletter produced by your local CCG Medicines Safety Officers .

Our aim is to highlight to you medication incidents that have occurred both locally and nationally, thus promoting and supporting safer practice.

Safe use of tiotropium prescribed as Braltus® using a Zonda® inhaler device

For some time Spiriva® (Handihaler) has been the only brand of dry powder tiotropium available for prescribing in the UK. However, recently a new brand of this medication has been released, called Braltus®. Braltus® contains the same ingredient (tiotropium) and the Zonda® inhaler device is very slightly different from the Spiriva® Handihaler, but it works in essentially the same way. As Braltus® is a more cost-effective product; many local CCG's have decided to switch patients from the Spiriva® brand to Braltus®.

Tiotropium as the Braltus® brand is described on the clinical system as being a 10microgram dose. Each capsule contains 16 micrograms of tiotropium bromide (the salt), equivalent to 13micrograms of tiotropium, but the delivered dose (the dose that leaves the mouthpiece of the Zonda® device) is 10micrograms.

Tiotropium (Spiriva) is described on the clinical system as being an 18microgram dose. Each capsule contains 22.5 microgram tiotropium bromide monohydrate (the salt) equivalent to 18microgram tiotropium. The delivered dose (the dose that leaves the mouthpiece of the HandiHaler® device) is 10micrograms.

Therefore, the delivered dose of tiotropium using Braltus® and Spiriva® are the same.

The patient will receive a new Zonda® inhaler device each month and are asked to safely dispose of the old one. This means that patients do not need to clean their Zonda® device. The devices are not interchangeable - tiotropium capsules (Spiriva) are not to be used in the Zonda inhaler and vice versa.

Healthcare professionals are reminded of the key points for Braltus® use via the Zonda® inhaler

There have been incidents reported locally whereby patients have used the new Zonda® inhaler device incorrectly, which has led to a potential risk of choking when using this product. This has occurred due to the capsule being placed directly into the mouthpiece instead of putting it into the chamber of the Zonda® inhaler device. Therefore, please be aware of the following & counsel patients accordingly:

- Please advise patients NEVER to insert the capsule directly into the mouthpiece, always follow the instructions provided with the inhaler.
- Braltus® capsules are in a pot rather than a blister pack.
- Braltus® capsules are transparent so it is easier to see if the full dose has been inhaled.

Learning the lessons - opioid use in non-cancer pain

South West Regional NHS has recently produced & circulated a Controlled Drugs newsletter highlighting Faye's Story & what can happen when things go wrong with prescribing for chronic pain –with lessons that must be learned by all healthcare professionals. The newsletter describes the inappropriate management of Faye's chronic pain following a back injury in 2009. Ultimately Faye had a respiratory arrest and died in 2013. Faye's parents felt that her medicines contributed to her death & key learning points were highlighted & considered by the GP practice involved:

⇒ Safe opiate prescribing
⇒ Role of oxycodone & dose equivalences of opiates
⇒ Alternatives to opiates for pain management
⇒ Mechanisms for reducing high doses of medication
⇒ Group discussions around difficult to manage cases

Faye's story was written after the findings of a coroner's inquest – her parents co-wrote this with the local NHS England CDAO as they were keen that lessons are learnt by all prescribers and no other family has to suffer a similar loss.

Demeclocycline

There has been a serious incident within the region when a patient with previously normal renal function was prescribed oral demeclocycline capsules 300mg three times a day, who then developed AKI one week after initiation. The patients U&Es were not checked during that time.

Advice for prescribers in primary care

(1) Demeclocycline should only be initiated by specialists.
(2) Where specialists have requested that GPs prescribe demeclocycline this should only occur if there is a clearly documented plan giving information on the monitoring and follow up of treatment.

Alert cards — DOAC s

In a recent incident reported nationally to NRLS, a lack of counselling may have contributed to a GI bleed and subsequent death of a patient recently started on a DOAC for atrial fibrillation.

The Nottinghamshire health community has recently adapted a standard DOAC information card to support provision of information to patients, carers and health professionals.

The card includes general and emergency information for patients of signs and symptoms of bleeding to be alerted to. Patients should be encouraged to have this card with them at all times and to show it to healthcare professionals prior to any consultation or procedure. For health professionals there are recommendations in relation to blood sampling.

Cards have been distributed to CCGs across the health community as well as community pharmacists.

Some CCGs have opted to have a copy of the card on their software systems , which they can print off as part of their patient consultation.

Valproate in women of child bearing age

Babies born to mothers who take valproate medicines (e.g. Epilim®, Depakote®) during pregnancy have a 30–40% risk of developmental disability and a 10% risk of birth defects.

The MHRA has issued communications about this in January 2015, February 2016 and again in April 2017.

The following advice is available for healthcare professionals:

- ◊ Do not prescribe valproate medicines for epilepsy or bipolar disorder in women and girls unless other treatments are ineffective or not tolerated; migraine is not a licensed indication
- ◊ Ensure women and girls taking valproate medicines understand the 30–40% risk of neurodevelopmental disorders and 10% risk of birth defects and are using effective contraception
- ◊ Valproate use in women and girls of childbearing potential must be initiated and supervised by specialists

An MHRA toolkit is available to support this advice. It includes

- ◊ Guidance for those prescribing and dispensing valproate
- ◊ Brochure for healthcare professionals
- ◊ Valproate guide for patients
- ◊ Prescriber Checklist
- ◊ Patient Card
- ◊ Template letter for women of childbearing age on valproate containing medicines (for use by GP practices)

Long-term nitrofurantoin—Recurrent UTIs

In some cases, patients may require prophylactic antibiotic treatment for recurrent UTIs and local antimicrobial guidelines recommend a 6 month course of nitrofurantoin as the first line option.

Nationally, a number of deaths have occurred due to pulmonary toxicity associated with long term nitrofurantoin use. In these cases, nitrofurantoin was added to repeat prescriptions without a planned stop or review date.

Patients prescribed nitrofurantoin as prophylactic treatment for recurrent UTIs should be counselled regarding the course length and should be advised to immediately report signs of respiratory and neurological toxicity (peripheral neuropathy, including optical neuritis).

It is strongly advised that a stop or review date is added to the patient's record and repeat prescription with monitoring of U&Es, LFTs and FBC test being performed every 3—6 months or as per local guidelines.

Action on receipt of alert notices from the Central Alerting System (CAS)

It is imperative that your organisation has a defined mechanism to ensure the contents of alerts received from CAS are reviewed by an appropriately qualified and/ or senior person.

Alerts should be reviewed, shared with all appropriate personnel and filed in a manner that they can be accessed for future reference.

Subsequent to receipt of these alerts, any actions taken, date of actions taken and details of personnel discharging these actions should be documented for future record and review. This record should include instances where no action has been taken, who reviewed the alerts and why this was appropriate to your organisation.

Please note that it is the responsibility of the Practice or Pharmacy to notify the local CAS team at NHS England of any change in contact details. Should you require any changes to be made to the email contact for your Practice or Pharmacy, please notify the local NHS England (North Midlands) team accordingly Contact

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Reminder: risk of serious interactions with itraconazole

Healthcare professionals are reminded of the risk of clinically significant drug interactions associated with the use of itraconazole.

A local case reported to the NRLS describes an incident where a GP was advised to treat oesophageal candida found during endoscopy and prescribed itraconazole. The patient was also taking rivaroxaban. When used in combination with itraconazole there is a risk of a major bleed. The local pharmacy highlighted the interaction to the GP who then prescribed fluconazole which does not interact with rivaroxaban.