Prescribing and Medicines Optimisation Guidance

Issue:112

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Safety guidance

1. MHRA Drug Safety Update - Valproate: review by two specialists is required for initiating valproate but not for male patients already taking valproate <u>LINK</u>

The Commission on Human Medicines (CHM) has advised that a review by two specialists remains in place for all patients less than 55 years of age **initiating valproate**, but that it will not be required for men who are already taking valproate, as there is already sufficient risk minimisation in place for this group.

It confirms that **males already established on valproate** do <u>not</u> require a risk assessment form (RAF) to be completed. It also clarifies that females who have a permanent reason for exclusion from the Pregnancy Prevention Programme (PPP) only require an ARAF (step one of form) to be completed ONCE only and this does not require a second specialist signatory.

Three helpful infographics have been produced to clarify these situations:

- for female patients under 55 years old
- for male patients under 55 years old
- for male and female patients 55 years and older

For additional advice on valproate prescribing in males, see previous bulletin LINK.

Key actions for prescribers involve the important communication of the risks of valproate to male patients, who are of reproductive potential. The MHRA have produced the following to facilitate these discussions/ communications:

- Advice for male patients on valproate to use contraception leaflet LINK and
- A visual risk communication diagram when counselling on the risks LINK

2. Promazine prescribing errors (where promethazine intended)

It has come to light that there have been some errors in the prescribing of promazine (where promethazine was the intended medication) in our ICB and wider neighbouring organisations, due to the similarity in name (and sedating properties) of these two "look alike sound alike" (LASA) medications.

Promazine is a first-generation (typical) antipsychotic, licensed for agitation and is rarely used. Conversely, promethazine (Phenergan) is a sedating antihistamine, licensed for treatment of allergic symptoms, sedation (short term only) and as an antiemetic.

Prescribing data (obtained via ePACT2 Sept-Nov 24) has highlighted thirty patients who were recently prescribed promazine in our ICB area. The Medicines Optimisation team are currently

facilitating a review of these "known" patients' clinical notes to check whether the prescribing of promazine was intentional. Any suspected errors will be flagged to prescribing leads. However, it would be prudent for all other practices to run a search for any promazine prescribing to ensure no further potential errors have occurred since the time frame of the ePACT2 data.

In light of these errors, promazine's formulary status is now under local review, along with Optimise Rx messaging to help avoid further "picking" errors, at the point of prescribing. Further communications will also go out to community pharmacy colleagues across our ICB area.

3. MHRA Drug safety update - GLP-1 and dual GIP/GLP-1 receptor agonists: potential risk of pulmonary aspiration during general anaesthesia or deep sedation LINK

Due to delayed gastric emptying, people taking GLP-1 and dual GIP/GLP-1 receptor agonists (dulaglutide, exenatide, liraglutide, lixisenatide, semaglutide and tirzepatide) may have residual gastric contents despite preoperative fasting. Healthcare professionals should be aware of the potential risk of pulmonary aspiration, and individual risk assessments should be completed.

National guidance

4. UKHSA Guidance: UK Access, Watch, Reserve, and other classification for antibiotics LINK

This guidance lists antibiotics in terms of whether they should be accessed, watched, or reserved. Where possible formularies, guidance and pathways should encourage empirical use of access antibiotics.

5. FSRH statement: Glucagon-like peptide-1 (GLP-1) agonists and oral contraception LINK

This statement from the Faculty of Sexual and Reproductive Health (FSRH), highlights that individuals using GLP-1 agonists should be advised to use contraception and be informed of the recommended 'washout' period. As tirzepatide has an effect on the bioavailability of oral contraceptives, an alternative method should be used, as described.

6. FSRH statement: Ulipristal acetate and breastfeeding LINK

FSRH recommends there is no need to avoid breastfeeding after taking a single dose of ulipristal acetate for emergency contraception, in line with recommendations from UK Drugs in Lactation Advisory Service (UKDILAS).

NICE guidelines

7. Epilepsies in children, young people and adults - updated guidance (NG217) LINK

Amended recommendations in line with MHRA guidance on use of valproate, valproate use in people younger than 55 years, valproate use in men, and the use of topiramate.

8. Gambling-related harms: identification, assessment and management (NG248) LINK

This guideline covers identifying, assessing and treating gambling-related harms. This includes people aged 18 and over who are experiencing gambling that harms, and people of any age affected by someone close to them who is experiencing gambling that harms.

9. Overweight and obesity management (NG246) LINK

This guideline covers the prevention and management of overweight, obesity and central adiposity in children, young people and adults. It brings together and updates all NICE's previous guidelines in this area but does not cover pregnancy.

10.Tobacco: preventing uptake, promoting quitting and treating dependence - updated guidance (NG209) LINK

This guidance has been updated to include cytisinicline (cytisine) as a medicinally licensed product to aid smoking cessation. Other recommendations on stop-smoking interventions and pharmacological support during pregnancy have been updated.

11.Early and locally advanced breast cancer: diagnosis and management – updated guidance (NG101) LINK

Points within the guidance for the identification, risk reduction and management of lymphoedema have been updated. This guidance updates and replaces NICE guideline CG80, and the section on lymphoedema in NICE guideline CG81 (both published in 2009).

Other

12.SPS: Hay fever or allergic rhinitis: treatment during pregnancy LINK

This updated resource discusses condition management, relevant guidelines, treatment options, monitoring in pregnancy, pregnancy outcome information and patient information. Pharmacological options include:

- **Topical treatment** with ocular mast cell stabilisers (sodium cromoglicate) or intranasal corticosteroids can be considered if non-pharmacological management is insufficient.
- If local topical therapy fails to control symptoms, oral antihistamines may be considered. **Loratadine** and **cetirizine** are the preferred antihistamines for pregnant women.

13. Hay fever season and the promotion of self-care- Reminder

The NHS England 2024 guidance on 'conditions for which over the counter (OTC) medicines should not routinely be prescribed in primary care' includes mild to moderate hay fever. LINK

Many preparations for the treatment of hay fever can be purchased by patients from pharmacies without a prescription, including fexofenadine 120mg tablets (when over 12 years of age). **These medications are often cheaper than the NHS prescription charge**.

Prescribers are encouraged to promote self-care of hay fever symptoms as the new season shortly begins. For patients unsure of hay fever symptoms and treatment, they can be referred into Minor Illness Pharmacy First in community pharmacy, where they can receive a consultation and discuss options of hay fever medicines they can purchase over the counter.

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