

# Staffordshire Medicines Safety Network Newsletter

June 2018

## Medicines Safety Network

Who are we and what we aim to do?

The Medicines Safety Officer Network is attended by MSO's from across healthcare organisations in Staffordshire. The role of the MSO in key roles is to promote the safe use of medicines across their Organisations. The Staffordshire network aims to look at the national and local medicines safety issues and provide a forum for sharing good practice, and discussing topical issues

## Summary Care Records and Clinical Trials/ Hospital Only Medication

Summary Care records should record if a patient is part of a clinical trial or being prescribed Hospital only 'red drugs'.

The MSO network are aware of incidents where patients have been prescribed two forms of the same medication because information on their participation in a clinical trial or information from their hospital discharge/

correspondence letter has not been inputted on the SCR. To ensure patient safety a record of this information should be included in a timely manner on the SCR.

## Focus on Anticoagulants

Anticoagulants have been the focus of discussions at the MSO Network in relation to patient safety. They are an a medication group where a significant number of errors are reported to the NRLS and locally errors are reported.

A recent error where a patient on Warfarin was prescribed 5mg and 1mg Warfarin tablets and took a dose 5x the intended prescribed strength has highlighted the need to carefully consider the strength of medication prescribed.

When prescribing Anticoagulants the MSO network would recommend that the following points are considered:

- Avoid co-prescribing with other anticoagulant medicines
- Ensure 1mg of warfarin is prescribed only

## Guidance for the use of Valproate in Female patients — Minimising the Risks

Valproate must no longer be used in any woman or girl able to have children unless she has a pregnancy prevention programme in place. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant.

- ✓ All female patients MUST be informed of, and understand:
- ✓ The risks associated with valproate during pregnancy
- ✓ The need to use effective contraception
- ✓ The need for regular review of treatment
- ✓ The need to rapidly consult if a pregnancy is planned or is confirmed

MHRA guidance states that valproate treatment must be started and supervised by a doctor experienced in managing epilepsy or bipolar disorder. The potential benefits of prescribing valproate MUST be carefully balanced against the risks when prescribing valproate for the first time, at routine treatment reviews, when a female child reaches puberty and when a woman plans pregnancy or becomes pregnant.

### **The MHRA Valproate toolkit—Support for all Clinicians:**

Communication materials have been developed to support discussion of these risks with women of childbearing potential and girls who take valproate. The [MHRA toolkit](#) aims to help ensure that female patients are better informed about the risks of taking valproate during pregnancy. The materials should be used to support discussion of the risks.

### **Support for Community Pharmacies:**

The Company Chemists' Association (CCA) has launched an audit tool for community pharmacy teams to use in reviewing their support for girls and women taking valproate medicines.

<https://pharmacysafety.org/2018/06/25/valproate-safety/>



## Latest Advice for Medicines Users - March 2018 - May 2018

**Daclizumab (Zinbryta) suspension and recall for safety reasons:** The European Medicines Agency (EMA) has recommended the immediate suspension of the marketing authorisation and recall of daclizumab (Zinbryta) in the EU following reports of serious inflammatory brain disorders, including encephalitis and meningoencephalitis, in patients with multiple sclerosis.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/686884/DSU-March-18-PDF.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/686884/DSU-March-18-PDF.pdf)

**Esmya (ulipristal acetate) for uterine fibroids:** do not initiate or re-start treatment; monitor liver function in current and recent users.

Temporary safety measures are in place while an EU review investigates the link between cases of serious liver injury, including 4 cases requiring liver transplantation, and Esmya for uterine fibroids.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/686884/DSU-March-18-PDF.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/686884/DSU-March-18-PDF.pdf)

**Head lice eradication products:** risk of serious burns if treated hair is exposed to open flames or other sources of ignition, eg, cigarettes

Pharmacists should tell people about the risk of fire when they discuss head lice eradication options.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/686884/DSU-March-18-PDF.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/686884/DSU-March-18-PDF.pdf)

**Confidential prescribing and patient safety reports on key indicators now available free for GPs:**

Confidential reports designed to help you improve the quality of your prescribing and patient safety are now available for practices that contribute to the MHRA's Clinical Practice Research Datalink. To receive the reports, practices must first join CPRD (<https://www.cprd.com/joiningform/contribute/default.aspx>)

**Valproate medicines (Epilim, Depakote):** contraindicated in women and girls of childbearing potential unless conditions of Pregnancy Prevention Programme are met. Valproate medicines must no longer be used in women or girls of childbearing potential unless a Pregnancy Prevention Programme is in place. Ensure all women and girls (and their parent, caregiver, or responsible person, if necessary) are fully informed of the risks and the need to avoid exposure to valproate medicines in pregnancy.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/701831/DSU-April-2018-PDF.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/701831/DSU-April-2018-PDF.pdf)

**Obeticholic acid (Ocaliva):** risk of serious liver injury in patients with pre-existing moderate or severe hepatic impairment; reminder to adjust dosing according to liver function monitoring

We are aware of reports of serious liver injuries and deaths in patients with primary biliary cholangitis with pre-existing moderate or severe liver impairment who were not adequately dose-adjusted. Follow dose reduction and monitoring advice in these patients to reduce the risk of serious liver injury.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/701831/DSU-April-2018-PDF.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/701831/DSU-April-2018-PDF.pdf)

**Valproate medicines (Epilim, Depakote):** Pregnancy Prevention Programme materials online

Use materials online now and hardcopies arriving over the coming weeks by post to ensure women and girls of childbearing potential on valproate medicines meet the requirements of the Pregnancy Prevention Programme.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/710841/DSU-May-PDF.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/710841/DSU-May-PDF.pdf)

**Braltus (tiotropium):** risk of inhalation of capsule if placed in the mouthpiece of the inhaler

Train patients to place the Braltus capsule in the correct chamber of the Zonda inhaler. We have received reports of patients who have inhaled a Braltus capsule from the mouthpiece into the back of the throat, resulting in coughing and risking aspiration or airway obstruction.

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/710841/DSU-May-PDF.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/710841/DSU-May-PDF.pdf)