

## MHRA drug safety updates from August & September 2023

### Reminder of the risk of very serious side effects from fluoroquinolones

Healthcare professionals prescribing fluoroquinolone antibiotics (ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, ofloxacin) are reminded to be alert to the risk of **disabling and potentially long-lasting or irreversible side effects**. Despite new [restrictions and precautions](#) introduced in 2019, a new study has shown no evidence of a change in fluoroquinolone prescribing patterns in the UK.

Do not prescribe fluoroquinolones for non-severe or self-limiting infections, or for mild to moderate infections (such as in uncomplicated cystitis, acute exacerbation of chronic bronchitis and chronic obstructive pulmonary disease) unless other antibiotics that are commonly recommended for these infections are considered inappropriate. Fluoroquinolone treatment should be discontinued at the first signs of a serious adverse reaction, including tendon pain or inflammation.

Healthcare professionals are also [reminded to be alert to the risk of psychiatric reactions](#), including depression and psychotic reactions, which may potentially lead to thoughts of suicide or suicide attempts. Advise patients to be alert to and report any mood changes, distressing thoughts, or feelings about suicide or harming themselves at any point during treatment.

### Methotrexate: advise patients to take precautions in the sun to avoid photosensitivity reactions

Photosensitivity reactions (including papular rash, sunburn, swelling) are known side effects of low and high dose methotrexate treatment and can be severe. Healthcare professionals, including those prescribing and dispensing methotrexate, should remind patients to take precautions to protect themselves from the sun and UV rays.

### Statins: very infrequent reports of myasthenia gravis

There have been a very small number of reports of new-onset or aggravation of pre-existing myasthenia gravis with preparations containing atorvastatin, pravastatin, lovastatin, fluvastatin, simvastatin, rosuvastatin and pitavastatin. Advise patients taking statins to be alert to new symptoms for myasthenia gravis, or worsening symptoms of pre-existing myasthenia gravis, and to seek medical advice if these occur.

More information on the topics above can be found in the MHRA [Drug Safety Updates](#) for August/Sept 2023.

## EMA PRAC recommends new measures to avoid topiramate exposure in pregnancy

The European Medicines Agency's safety committee (PRAC) recommends new measures to avoid exposure of children to topiramate-containing medicines in the womb. It is already well known that topiramate can cause major congenital malformations and foetal growth restriction when used during pregnancy, but recent data also suggest increased risk of neurodevelopmental disorders following topiramate use during pregnancy.

The recommendations are that:

- Patients taking topiramate for any indication should use highly effective contraception during treatment and for at least 4 weeks after stopping topiramate treatment.
- When used for prevention of migraine, topiramate is contraindicated during pregnancy. It must be discontinued if the patient becomes pregnant or is planning for a baby.
- When used for epilepsy, topiramate treatment should only continue during pregnancy if there is no suitable treatment alternative.
- Searches to identify people can be found in SystemOne GPs > CQC > Safety Alerts

The PRAC has also recommended a pregnancy prevention programme for topiramate. **A direct healthcare professional communication will be sent in due course to healthcare professionals prescribing, dispensing or administering the medicine.**

## Wound Care Products Template and step by step guide

All staff issuing dressings on SystmOne are encouraged to use the SystmOne template 'Wound Care Products - DCCG V2 template' to help increase adherence to the formulary; this should make it easier to select formulary choice dressings from the wide range of dressings available. The template contains links to additional resources and there are helpful notes next to each category of dressing (for example if secondary dressings are necessary, or specific contraindications to a dressing type). For further help with understanding how to use the template and how to manage non-formulary requests the Medicines Optimisation Team have developed a step by step guide available [here](#).

## Reminder: SMR dashboard available via the Diis

The Structured Medication Review (SMR) dashboard is available to view, via the Dorset Intelligence & Insight Service (Diis). The dashboard is intended to provide benchmarking data to aid the targeting of structured medication reviews to 'at risk' populations. The dashboard includes snapshots of SMR eligibility and delivery, as well as data mapped by PCN and clinician role. The dashboard can be accessed via the Diis portal. Practices are encouraged to benchmark and review patient recall processes to ensure that SMRs carried out are for patients most at risk as set out in the [network contract DES](#) and the [Investment and Impact fund \(IIF\)](#). If you have not yet registered for the Diis then you can do so via [this link](#).

### Shortages/supply disruptions

- Midazolam (Epistatus®) 2.5mg/0.25ml and 10mg/1ml oromucosal solution pre-filled oral syringes are out of stock until late November 2023. The 2.5mg/0.5ml (Buccolam® and generic) and 10mg/2ml (Buccolam®) oral syringes remain available and will be able to support increased demand. Please note the difference in volume between Epistatus® and Buccolam® and that patient/carer education that is required for administration of Buccolam®.
- Permethrin 5% w/w cream is in limited supply until further notice due to an increase in demand. The [medicine supply notification](#) includes information on the available unlicensed products and the current availability of alternative treatments.

### CPD / learning resources

- [PrescQIPP Bulletin 332: Preparing GP practices for a regulatory inspection](#) (free PrescQIPP account needed). This bulletin describes considerations for GP practices who are undergoing a CQC inspection. It sets out resources that can be used to demonstrate safe medicines management in line with the CQC Key Lines of Enquiry (KLOE).

### Quick bites

- The Dorset Formulary is available at: [www.dorsetformulary.nhs.uk](http://www.dorsetformulary.nhs.uk).
- Please complete this short 30 second survey to support our understanding of how the formulary is used in Dorset: <https://www.surveymonkey.co.uk/r/C5Z6MBG>
- [Autumn/Winter 2023-24 flu and COVID-19 seasonal campaign](#) Letter setting out next steps for flu and Covid-19 vaccine delivery for Autumn/Winter 2023/24 asks that both commence in October for adults; flu vaccines for children should start from September. The age cohorts for both have been aligned, allowing for co-administration.
- [Routine childhood immunisation schedule](#) – updated to include the revised human papillomavirus HPV schedule from 1 September 2023.

### REGIONAL MEDICINES INFORMATION SERVICE

If you work in primary care (including community pharmacy), specialist medicines advice can be obtained from SPS via **0300 7708564** or email [asksp.nhs@sps.direct](mailto:asksp.nhs@sps.direct). (Staff in Dorset NHS Trusts should seek advice from their pharmacy teams).