

## Medicines Safety Assurance Tool

February 2022

To request this safety tool, or for more information about this tool, to make a comment, or share a safety issue please contact [mlcsu.medicines-safety@nhs.net](mailto:mlcsu.medicines-safety@nhs.net)



Midlands and Lancashire  
Commissioning Support Unit

### Weight-based medication errors in children

03 February 2022

Investigation was launched following errors in the prescription, dispensing and administration processes leading to a 4-year old child receiving 10 times the intended dose of anticoagulant on five separate occasions over three days, resulting in a non-fatal bleed on brain.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



Action taken

Status

Action due date

Date completed

### Hydroxychloroquine, chloroquine: increased risk of cardiovascular events when used with macrolide antibiotics; reminder of psychiatric reactions

15 February 2022

MHRA advise clinicians to carefully consider benefits & risks before prescribing systemic azithromycin or other macrolides to patients on hydroxychloroquine or chloroquine. An observational study has shown co-administration is associated with increased cardiovascular mortality.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)



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### Unintentional overdose of paracetamol in adults with low bodyweight

24 February 2022

Adult inpatients with low bodyweight (less than 50kg) and the risk of liver toxicity from oral paracetamol is the focus of this investigation, which specifically focuses on the dose prescribed and the processes for ensuring weight is accurately recorded.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
 Practice audit/search  Other (please specify)

Action taken

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## Summary of Product Characteristics updates

### Adartrel (ropinirole) film-coated tablets

SPC has been updated to note patients should be regularly monitored for the development of mania; symptoms can occur with or without the symptoms of impulse control disorders. A new paragraph on dopamine agonist withdrawal syndrome has also been added.

### Aldactone (spironolactone) Tablets

SPC updated to note that spironolactone binds to the androgen receptor and may increase prostate specific antigen (PSA) levels in abiraterone-treated prostate cancer patients; use with abiraterone is therefore not recommended.

### Clexane (enoxaparin)- all presentations

SPC updated to warn acute generalised exanthematous pustulosis reported (unknown frequency); patients should be advised of signs/symptoms & monitored for skin reactions, enoxaparin should be withdrawn immediately & alternative treatment considered (as appropriate), if this occurs.

- Newsletter  Optimise Rx/ScriptSwitch  
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### Co-Amilozide 2.5mg-25mg (amiloride/hydrochlorothiazide) Tablets

SPC now notes acute respiratory toxicity as a very rare potential adverse effect of treatment with hydrochlorothiazide. Symptoms include dyspnoea, fever, pulmonary deterioration and hypotension. If suspected, hydrochlorothiazide treatment should be stopped.

### Epilim (sodium valproate) – all formulations and strengths

SPC updated with interaction with metamizole which may decrease sodium valproate levels with concomitant administration; prescribers advised to monitor clinical response and consider monitoring sodium valproate levels as appropriate.

### Eyreida (bimatoprost) 0.3mg/ml eye drops, solution

SPC now includes new information on the adverse events prostaglandin analogue periorbitopathy and iris hyperpigmentation, and notes that patients should be informed of the possibility of these occurring; some changes may be permanent.

### Glucophage (metformin) 500 mg film coated tablets

SPC has been updated to allow the use of metformin if clinically needed during pregnancy and in the periconceptional phase.

### Lumigan (bimatoprost) eye drops

SPC notes patients should be informed of the possibility of prostaglandin analogue periorbitopathy & increased iris pigmentation. Changes may be permanent, and may lead to impaired field of vision and differences in appearance between the eyes when only one eye is treated.

### Mometasone furoate 50 microgram/ actuation nasal spray

SPC updated to state that the suspension contains benzalkonium chloride which may cause irritation or swelling inside the nose especially if used for a long time.

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### Nuvaring vaginal delivery system (ethinylestradiol, etonogestrel)

SPC now notes concomitant use with medicinal products containing glecaprevir/pibrentasvir is contraindicated owing to increased risk of ALT elevations. Frequency of the adverse effect of urticaria has been updated from unknown to uncommon.

### Oruvail (ketoprofen) 100 mg Prolonged-Release Hard Capsules

SPC updated to note increased risk for severe complications (e.g. GI ulceration) in patients receiving nicorandil and NSAIDs concomitantly, and that caution is advised when using with cardiac glycosides (CG) as NSAIDs may reduce renal function and decrease renal CG clearance.

### Saxenda (liraglutide) 6 mg/mL solution for injection in pre-filled pen

Headache has been added as a very common adverse reaction reported in adults.

### Suboxone (buprenorphine/naloxone) – all presentations

Paragraph on seizures and on drug withdrawal syndrome have been added, as has advice that patients should be informed of signs and symptoms of overdose and ensure family/friends are also aware of these signs and to seek immediate medical help if they occur.

### Tridestra (medroxyprogesterone acetate/ estradiol valerate) Tablets

SPC updated with warning that exogenous oestrogens may induce or exacerbate symptoms of hereditary and acquired angioedema and a new sub-section has been added on ALT elevations linked to use of combination regimen ombitasvir/paritaprevir/ritonavir with and without dasabuvir.

### Warfarin Sodium 1mg/1ml Oral Suspension

SPC updated to note acute kidney injury may occur in patients with altered glomerular integrity or with a history of kidney disease (few cases reported in those with no pre-existing disease). Close monitoring is advised in patients with a supratherapeutic INR and haematuria.

Please note that the information in this Safety log is correct at the time of publication. Clinicians should always refer to the most up to date information.

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### Zaluron XL (quetiapine)– 50mg, 300mg and 400mg strengths

SPC updated to include cardiomyopathy, myocarditis and cutaneous vasculitis as potential side effects with unknown frequency.

### About this document

MLCSU collates and shares the latest current awareness and evidence-based medicines information from NICE and UKMi relating to medicines safety each month.

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