

## Medicines Safety Assurance Tool

April 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)

### Inadvertent Oral Administration Of Potassium Permanganate

05 April 2022

These concentrated forms of potassium permanganate resemble oral tablet or drink & if ingested are highly toxic. Alert asks secondary & primary care providers to take action to assess if use can be reduced; to ensure safer prescribing & labelling, & to ensure it is stored safely.

Proposed action

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



Action taken

Status

Action due date

Date completed

### Urgent public health message - Hepatitis: increase in acute cases of unknown aetiology in children

08 April 2022

Urgent public health message to all GP practices and paediatric services regarding an increase in acute hepatitis cases of unknown aetiology in children. Contains information on symptoms, testing and referral

Proposed action

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



Action taken

Status

Action due date

Date completed

## Medicines Safety Assurance Tool

April 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)

### Pregabalin (Lyrica): findings of safety study on risks during pregnancy

20 April 2022

A new study has suggested pregabalin may slightly increase the risk of major congenital malformations if used in pregnancy. Patients should continue to use effective contraception during treatment and avoid use in pregnancy unless clearly necessary.

Proposed action

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



Action taken

Status

Action due date

Date completed

### Unintentional overdose of morphine sulfate oral solution

28 April 2022

Report aims to help improve safe use of oral morphine sulfate solution. The reference event concerned 89-year old patient who took an accidental and fatal overdose after mistaking manufacturer's text on bottle for the dose and not noticing dispensing label affixed to outer box.

Proposed action

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



Action taken

Status

Action due date

Date completed

## Medicines Safety Assurance Tool

April 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)

### Summary of Product Characteristics updates

#### Accupro (quinapril) and Accuretic (hydrochlorothiazide/quinapril) tablets

SPC recommends monitoring serum sodium regularly in older patients and those at risk of hyponatraemia as Syndrome of Inappropriate Anti-Diuretic Hormone and subsequent hyponatraemia has been observed. The information on psoriasis has also been updated.

#### Adoport (tacrolimus) Hard Capsules

SPC updated to include a new section on nephrotoxicity, a new section on interaction with flucloxacillin, and additional safety information regarding co-administration with other agents that increase serum potassium. SPC also now notes cases of CMV infection have been reported.

#### Brilique (ticagrelor) 90 mg and 60 mg film coated tablets

SPC updated to include adverse effects bradyarrhythmia and AV block of unknown frequency and corresponding information under special warnings and cautions for use.

#### Brintellix (vortioxetine hydrobromide) film-coated tablets – all strengths

SPC updated to include adverse effects hyperprolactinaemia and headache of unknown frequency and hyperhidrosis (common frequency).

#### FemSeven Conti (estradiol/ levonorgestrel) 50 micrograms/7 micrograms/24 hours, transdermal patch

SPC updated to warn of potential to exacerbate symptoms of hereditary and acquired angioedema. Details of potential to interact with glecaprevir/pibrentasvir have also been added.

Proposed action

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



Action taken

Status

Action due date

Date completed

## Medicines Safety Assurance Tool

April 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)

### Glucophage SR (metformin) prolonged release tablets- all strengths

Updated to include warning metformin may reduce vit B12 serum levels. In case of suspicion of deficiency (such as anaemia or neuropathy), serum levels should be monitored. Periodic vit B12 monitoring could be necessary in patients with risk factors for deficiency.

### Glycopyrronium bromide 1mg/5ml Oral Solution

This healthcare professional checklist is an aid to help evaluate and discuss the risks associated with glycopyrronium bromide oral solution with the patient's carer and includes the management and minimisation of adverse effects and instructions on how to administer.

### IMVAGGIS (estriol) 0.03 mg Pessary

The special warnings section (4.4) has been updated to include the statement: "Exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema".

### Inhixa (enoxaparin) solution for injection products

Updated with licence extension to cover extended treatment of deep vein thrombosis and pulmonary embolism, and prevention of its recurrence, in patients with active cancer.

### Innozide 20/12.5 mg (enalapril/hydrochlorothiazide) Tablets

SPC updated to note that very rare severe cases of acute respiratory toxicity, including acute respiratory distress syndrome (ARDS), have been reported after taking hydrochlorothiazide. If ARDS is suspected, treatment should be withdrawn and appropriate treatment given.

### Kenalog (triamcinolone) Intra-articular / Intramuscular Injection

SPC warns endophthalmitis, eye inflammation, increased intraocular pressure, chorioretinopathy, including crystalline maculopathy & viral retinitis and vision loss have been reported with intravitreal administration. Administration via intraocular injection is contraindicated.

## Medicines Safety Assurance Tool

April 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

### Marvelon and Mercilon (ethinylestradiol/desogestrel) Tablets

SPCs updated to warn that exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema.

### Octasa (mesalazine) 1600 mg modified-release tablets

SPC updated to warn severe cutaneous adverse reactions, including Stevens-Johnson syndrome & toxic epidermal necrolysis have been reported with mesalazine; treatment should be discontinued, at first appearance of severe skin reactions or any other sign of hypersensitivity.

### Pregabalin Rosemont 20mg/ml Oral Solution

Severe cutaneous adverse reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, which can be life-threatening or fatal, are noted as a potential adverse effect of treatment (rare). If suggestive symptoms develop pregabalin should be withdrawn immediately.

### Sativex (delta-9-tetrahydrocannabinol/cannabidiol) Oromucosal Spray

SPC now advises each actuation contains up to 40mg ethanol, equivalent to 50% by volume (~480mg/maximal daily dose for 70kg adult equivalent to ~10mL beer/5mL wine), considered a small amount that will not have any noticeable effects. Also contains 52mg propylene glycol/100µL spray.

### Seroquel XL (quetiapine) – all strengths

SPC updated to include confusional state as an adverse reaction with an uncommon frequency.

### Selincro (nalmefene) tablets

Visual impairment has been added as a potential adverse effect of treatment (frequency unknown). It is usually transient if it occurs.

### Synjardy (empagliflozin/metformin) film-coated tablets- all strengths

Updated to warn empagliflozin may increase renal lithium excretion and blood lithium levels may be decreased, therefore serum lithium levels should be monitored more frequently after empagliflozin initiation and dose changed if required. Tubulointerstitial nephritis added as ADR.

## Medicines Safety Assurance Tool

April 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)

### [Trelegy Ellipta \(fluticasone, vilanterol, umeclidinium\) 92 micrograms/55 micrograms/22 micrograms inhalation powder, pre-dispensed](#)

SPC updated to include adverse effects dysgeusia (taste disturbance), glaucoma and eye pain of uncommon frequency and raised intraocular pressure of rare frequency.

### [Utrogestan \(micronized progesterone\) Vaginal 200mg Capsules](#)

SPC updated with new indication for the prevention of preterm birth in women with a singleton pregnancy who have a short cervix (mid-trimester sonographic cervix  $\leq 25$  mm) and/or a history of spontaneous preterm birth.

### [Vitamin E Suspension 100mg/ml](#)

SPC updated with advice to adjust dose to maintain serum  $\alpha$ -tocopherol:cholesterol ratio above 5.4 mg/g and to monitor serum levels at least annually and 3-6 months after dose changes.

### [Zithromax \(azithromycin\) Powder for Oral Suspension and capsules](#)

SPC updated in line with recent MHRA review of cardiovascular safety and now notes advice to carefully consider balance of benefits and risks of co-administration with hydroxychloroquine or chloroquine due to increased risk of cardiovascular events and mortality.

### [Zyban \(bupropion hydrochloride\) 150 mg prolonged release tablets](#)

SPC updated to note that acute generalised exanthematous pustulosis has been reported as an adverse effect (frequency unknown).

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.

Copyright © Midlands and Lancashire Commissioning Support Unit

## Medicines Safety Assurance Tool

April 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

### 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.

© NICE 2022. All rights reserved. Subject to [Notice of rights](#).

NICE guidance is prepared for the National Health Service in England. All NICE guidance is subject to regular review and may be updated or withdrawn. NICE accepts no responsibility for the use of its content in this product/publication.