

Medicines Safety Assurance Tool

October 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

DTB select: More concerns over safety of topiramate in pregnancy

12 October 2022

Commentary is provided for a cohort study that found increased risk of neurodevelopmental disorders in children of mothers exposed to topiramate in pregnancy. MHRA are reviewing the need for any additional measures to reduce the potential harms of topiramate during pregnancy.

Proposed action

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



Action taken

Status	Action due date	Date completed

Herbal Medicines: Safety during pregnancy

12 October 2022

Web resource reviews the safety of commonly used herbal medicines during pregnancy, including considerations for expectant mothers, such as potential interactions, and general advice such as choosing products from a reputable source.

Proposed action

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



Action taken

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Healthcare Safety Investigation Branch (HSIB) local investigation pilot: shared learning for local healthcare systems

13 October 2022

The final evaluation report shares in-depth findings and learning drawn from investigations done over the last year that may be of benefit to local healthcare systems, individual organisations and recently formed Integrated Care Systems.

Proposed action

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



Action taken

Status

Action due date

Date completed

Consultation on how MHRA communicate with healthcare professionals to improve medicines and medical devices' safety

14 October 2022

The MHRA is reviewing its approach to engagement with healthcare professionals (HP) to improve safety of medicines and medical devices. Consultation seeks views on how HPs want to receive safety information, how they'd like to be engaged, and feedback on the Yellow Card system.

Proposed action

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



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DTB select: Safety update on home use of nebulisers for acute asthma treatment in children

20 October 2022

Summary and context provided on MHRA Drug Safety Update which advised healthcare professionals that nebulised rescue medication for asthma should only be used at home under management from an asthma specialist.

Proposed action

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



Action taken

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Date completed

Comirnaty and Spikevax: heavy menstrual bleeding added as a side effect

28 October 2022

Heavy menstrual bleeding has been reported after 1st, 2nd & booster doses of Comirnaty & Spikevax. The PRAC has recommended this should be added to product information as a side effect of unknown frequency. There is no evidence to suggest any impact on reproduction and fertility.

Proposed action

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



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Risk Minimisation Materials

[Drovelis \(3 mg/14.2 mg drospirenone and estetrol monohydrate\) film-coated tablets: Checklist for prescribers](#)

This checklist should be used alongside the SPC during combined hormonal contraceptive consultations. It covers assessment of thromboembolism risk and information that should be given to the patient, including factors that increase risk.

Proposed action

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



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Summary of Product Characteristics

[Asacol \(mesalazine\) 400mg MR Tablets](#)

SPC updated to warn cases of nephrolithiasis have been reported with use of mesalazine, including stones of 100% mesalazine content; adequate fluid intake is recommended during treatment.

[Crestor \(rosuvastatin\) all strength film-coated tablets](#)

SPC now advises that ticagrelor might affect renal excretion of rosuvastatin, increasing the risk for rosuvastatin accumulation. Although the mechanism is unknown, in some cases, concomitant use has led to impaired renal function, increased CPK level and rhabdomyolysis.

[Dexamfetamine sulfate tablets](#)

SPC now notes that amphetamines can cause a significant elevation in plasma corticosteroid levels, and that this increase is greatest in the evening. Also, amphetamines may interfere with urinary steroid determinations.

Proposed action

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



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Erythroped A (erythromycin) 500 mg tablets

There have been several revisions, including addition of information on the potential for an increased risk of cardiovascular events when macrolides are used in combination with hydroxychloroquine or chloroquine, and data from observational studies on exposure during pregnancy.

GANFORT 0.3 mg/ml bimatoprost + 5 mg/ml timolol maleate eye drops, solution- all presentations

Details of adverse effect already listed in SPC have been expanded to advise that periorbital and lid changes associated with periorbital fat atrophy and skin tightness result in deepening of eyelid sulcus, eyelid ptosis, enophthalmos and eyelid retraction.

Lenzetto (estradiol) 1.53 mg/spray, transdermal spray, solution

SPC updated to reinforce warning that estradiol spray can be accidentally transferred to children from area of skin where it was sprayed on, and to advise on avoidance measures, and to seek medical care if exposed child experiences breast development or other sexual changes.

Lyxumia (lixisenatide) 20 micrograms solution for injection

SPC updated with delayed gastric emptying as a rare adverse effect.

Medikinet (methylphenidate) tablets- all strengths

Epistaxis has been added to SPC as an adverse effect of unknown frequency.

Norimin & Synphase (norethisterone/ethinylestradiol) Tablets

SPC for both products notes that exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema (frequency unknown) and therefore caution is advised.

Nuvaxovid (SARS-CoV-2 recombinant spike protein) dispersion for injection, COVID-19 Vaccine (recombinant, adjuvanted)

SPC updated with extension of indication to cover the population of adolescents aged 12 to 17 years.

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[Priadel \(lithium citrate\) liquid and tablets – all strengths](#)

SPC updated with addition of warning that concomitant administration with dapagliflozin may decrease serum lithium levels due to an increase in lithium renal clearance.

[Sandrena \(estradiol\) 0.5 and 1.0 mg gel](#)

Addition of ethanol to excipients list & info on accidental transfer of gel to others, exacerbation of symptoms of hereditary/acquired angioedema by exogenous oestrogens, ALT elevations & co-administration with HIV protease inhibitors, as well as update of info on breast cancer.

[Spikevax \(elasomeran\)](#)

SPC now notes the high-dose quadrivalent influenza vaccine can be concomitantly administered with Spikevax.

[Suliqua \(insulin glargine, lixisenatide\) solution for injection in a pre-filled pen- all strengths](#)

Delayed gastric emptying has been added to SPC as a rare adverse effect.

[Xaluprine \(mercaptopurine\) oral suspension](#)

Erythema nodosum has been added as a potential adverse effect of treatment (unknown frequency).

[Vagirux \(estradiol\) 10 micrograms vaginal tablets](#)

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

[Zoton \(lansoprazole\) FasTab 15 mg](#)

DRESS (drug reaction with eosinophilia and systemic symptoms) and tubulointerstitial nephritis have been added as adverse drug reactions to the SPC.

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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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.

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