

## Medicines Safety Assurance Tool

January 2023

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

### [DTB select: Safety warning - combination products containing codeine and ibuprofen](#)

03 Jan

Article discusses new safety measures for codeine/ibuprofen combination products, recommended by the European PRAC, following a review of cases of toxicity associated with their abuse and dependence. It is not known if the MHRA will issue similar guidance in the UK.

Proposed action

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



Action taken

Status	Action due date	Date completed

### [Xaqua \(metolazone\) 5mg tablets: exercise caution when switching patients between metolazone preparations](#)

25 Jan

Prescribers and dispensers should use caution if switching patients between different metolazone preparations as the rate and extent of absorption of metolazone are formulation dependent. This can impact the bioavailability of the product.

Proposed action

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



Action taken

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### Topical testosterone (Testogel): risk of harm to children following accidental exposure

25 Jan

Premature puberty and genital enlargement have been reported in children who were in close physical contact with an adult using topical testosterone and who were repeatedly accidentally exposed to this medicine. To reduce these risks, advise patients to wash their hands after application of topical testosterone, cover the application site with clothing once the product has dried, and wash the application site before physical contact with another adult or child.

Proposed action

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



Action taken

Status

Action due date

Date completed

### Electronic Prescribing and Medicines Administration Systems: report adverse incidents on a Yellow Card

25 Jan

We ask healthcare professionals to be vigilant to adverse incidents involving software, apps, and artificial intelligence (AI) as medical devices and to report incidents to us via the Yellow Card scheme.

Proposed action

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



Action taken

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### Risk Minimisation Materials updates

#### Checklist for healthcare professionals prescribing glycopyrronium bromide oral solution

A checklist is provided to support healthcare professionals mitigate the risk that patients prescribed this medicine will experience anticholinergic side effects. A reminder card for patients is also available providing advice on how to manage common side effects.

Proposed action

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



Action taken

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### Summary of Product Characteristics updates

#### Abilify (aripiprazole) – all formulations

SPCs updated to include decreased blood prolactin as an uncommon adverse event.

#### Allevia (fexofenadine hydrochloride) 120mg tablets

SPC updated to state this is licensed for the treatment of adults and children 12 years and older for the relief of symptoms associated with allergic rhinitis (previously seasonal allergic rhinitis).

#### Anoro Ellipta 55 micrograms/22 micrograms (umeclidinium/vilanterol) inhalation powder, pre-dispensed

Eye pain and muscle spasms have been added to SPC as adverse reactions, of rare and uncommon frequency, respectively.

Proposed action

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



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### Boots Ibuprofen 400 mg Tablets

SPC updated to note renal tubular acidosis and hypokalaemia may occur following acute overdose and use over long periods at high doses, and to note that from the 20th week of pregnancy, ibuprofen use may cause oligohydramnios resulting from foetal renal dysfunction.

### Crestor (rosuvastatin) 5mg film-coated tablets

Interactions section updated with information on effects of concomitant use of the following on rosuvastatin exposure (AUC): teriflunomide (2.5-fold increase), capmatinib (2.1-fold increase), fostamatinib (2.0-fold increase) and febuxostat (1.9-fold increase).

### Fycompa (perampanel) preparations

Hallucinations has been added to the list of potential adverse effects (frequency uncommon).

### GlucaGen (glucagon) Hypokit 1 mg

SPC updated with a new warning of 'hyperglycaemia' in patients with diabetes mellitus when used as a diagnostic aid; this is an extension of the known pharmacological action of GlucaGen. Injection site reactions were added as an adverse effect (frequency not known).

### Imodium (loperamide) products

SPC now warns that upon cessation, cases of drug withdrawal syndrome have been observed in individuals abusing, misusing, or intentionally overdosing with excessively large doses of loperamide.

### Incruse Ellipta (umeclidinium) 55 micrograms inhalation powder, pre-dispensed

Anaphylaxis has been added to SPC as a rare adverse reaction.

### Infanrix hexavalent vaccine (DTaP/IPV/Hib/HepB)

SPC updated with new excipients: para-aminobenzoic acid which may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm, and phenylalanine which may be harmful in patients with phenylketonuria.

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### Luforbec (beclomethasone/formoterol) 100/6 micrograms per actuation pressurised inhalation solution

SPC updated to include data from a 12-week study in adolescent asthma patients, and data from an experimental formulation (50micrograms beclomethasone/ 6mcg formoterol) in children aged 5-11 years. However no recommendation on a posology in these age groups can be made.

### Madopar CR 100 mg/25 mg (levodopa/ benserazide) Prolonged Release Hard Capsules

SPC updated to note a delayed, but longer persistent effect is observed when it is taken with a protein-rich meal. Maximum plasma concentrations occur on average two hours later after postprandial administration when compared to administration on an empty stomach.

### Nasacort (triamcinolone) 55 micrograms/dose, nasal spray, suspension

SPC updated to include the risks associated with sudden discontinuation of corticosteroids (CS) after prolonged use, noting such effects are extremely rare for nasal corticosteroids, and much less likely to occur with nasal corticosteroids than with oral corticosteroids.

### Neoral (ciclosporin) products

Hearing impairment has been added to SPCs as a new undesirable effect of unknown frequency.

### Nicorette (nicotine) QuickMist mouthspray

Various changes have been made to the SPC in line with the additional approval of the mouthspray for use to relieve/prevent craving and withdrawal symptoms in those with nicotine dependence arising from use of electronic cigarettes.

### Pariet (rabeprazole)- all strengths

SPC updated to note acute tubulointerstitial nephritis (TIN), which can progress to renal failure, has been observed in patients taking rabeprazole. If TIN is suspected, rabeprazole should be discontinued and appropriate treatment promptly initiated.

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### Plavix (clopidogrel) 75 and 300 mg film-coated tablets

SPC now warns that due to the increased risk of haemorrhage, triple antiplatelet therapy (clopidogrel + aspirin + dipyridamole) for stroke secondary prevention is not recommended in patients with acute non-cardioembolic ischemic stroke or TIA.

### Rybelsus (semaglutide)- all strengths

SPC updated with inclusion of 'hypersensitivity' as an uncommon adverse drug reaction.

### Solu-Cortef (hydrocortisone sodium succinate)

SPC updated to highlight that doses vary according to the condition and patient status, thus dosage adjustments are necessary. The lowest dose should be given for the shortest duration. Advice is given regarding abrupt discontinuation with reference to risk of fatal outcomes.

### Trusopt (dorzolamide hydrochloride) – all preparations

Updated with addition of tachycardia & hypertension as adverse effects of unknown frequency & instructs when using nasolacrimal occlusion or closing eyelids for 2 mins, systemic absorption is reduced which may result in decreased systemic side effects & increased local activity.

### Valtrex (valaciclovir) preparations

Tubulointerstitial nephritis has been added to the list of potential adverse effects (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.

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### 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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