

## Medicines Safety Assurance Tool

September 2021

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)

### Topical corticosteroids: information on the risk of topical steroid withdrawal reactions

15 September 2021

Rarely, severe adverse effects can occur on stopping treatment with topical corticosteroids, often after long-term continuous or inappropriate use of moderate to high potency products. To reduce the risks of these events, prescribe the topical corticosteroid of lowest potency needed and ensure patients know how to use it safely and effectively.

Proposed action

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



Action taken

Status

Action due date

Date completed

### Clexane® (enoxaparin sodium) device

15 September 2021

Important Information regarding differences between PREVENTIS and ERIS needle guard safety system

Proposed action

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



Action taken

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### Safety of topical medicines in porphyria

24 September 2021

This resource discusses considerations that need to be made when prescribing or administering topical treatments to individuals with porphyria, and links to useful resources.

Proposed action

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



Action taken

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## Summary of Product Characteristics updates

### Ationdo (tapentadol) SR prolonged release tablets – All strengths

SPC updated with addition of neonatal withdrawal syndrome (NOWS) which can be experienced by newborns post long term maternal exposure to tapentadol. NOWS can be life threatening if not recognised and treated and an antidote should be readily available for these cases.

### Audavate (betamethasone) 0.1% w/w Cream

Sections 4.4 and 4.8 have been updated to include information about the risks and characteristics of topical steroid withdrawal reactions, which the MHRA has requested be added to the SPCs and patient information leaflets of all topical corticosteroid medicines.

Proposed action

- Newsletter  Optimise Rx/ScriptSwitch  
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### Betacap (betamethasone valerate) Scalp Application

SPC now warns that long term continuous or inappropriate use of topical steroids can result in development of rebound flares after stopping treatment (topical steroid withdrawal syndrome) which takes the form of a dermatitis with intense redness, stinging and burning.

### Blissel (estriol) 50 micrograms/g vaginal gel

SPC updated with new data which suggest there is no increase in risk of breast cancer in women with no history of breast cancer taking low dose vaginally applied oestrogens. However, it is unknown if low dose vaginal oestrogens stimulate recurrence of breast cancer.

### Brolene (propamide isethionate) Eye Drops

SPC updated to note this product contains benzalkonium chloride, which may be absorbed by (and change the colour of) soft contact lenses, and may cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface.

### Ciproxin (ciprofloxacin) 500 mg film-coated tablets

SPC updated to note if a dose is missed, it should be taken anytime but not later than 6 hours prior to the next scheduled dose. If less than 6 hours remain before the next dose, the missed dose should not be taken and treatment should be continued as prescribed.

### Fucidin (fusidic acid) 250 mg/5 ml Oral Suspension

Angioedema, pruritis and erythema have been added as rare adverse events and the warnings section has been updated to include information on sorbitol (source of fructose), benzyl alcohol and sodium content

### Imuran (azathioprine) preparations

Erythema nodosum has been added as a potential adverse effect of treatment (frequency not specified).

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### Mucodyne (carbocisteine) syrup

Excipients with known effects updated to include ethanol, amount in 5 ml of this medicine is equivalent to less than 1.7 ml beer or 0.68 ml wine. Methyl parahydroxybenzoate also included in excipients which may cause allergic reactions (possibly delayed).

### Nicorette (nicotine) products

SPCs have been updated to include seizures as an undesirable effect (unknown incidence) and to state the potential risks and benefits of nicotine should be carefully evaluated before use in subjects with a history of epilepsy.

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

SPC now states 600mg loading dose is not recommended in patients with non-ST segment elevation acute coronary syndrome and  $\geq 75$  years of age due to increased bleeding risk. It also advises that in patients on clopidogrel, it might take longer than usual to stop bleeding.

### Seroquel and Seroquel XL (quetiapine) – all presentations

Cardiomyopathy, myocarditis, and cutaneous vasculitis have been added as adverse drug reactions (frequency not known). Although a causal relationship has not been established, in patients with suspected cardiomyopathy or myocarditis, discontinuation should be considered.

### Shingrix powder and suspension for injection, Herpes zoster vaccine (recombinant, adjuvanted)

Section 4.4 has been updated to remove the statements referring to the availability of limited data to support the use of Shingrix in frail individuals including those with multiple comorbidities.

### Siklos (hydroxycarbamide) 100 and 1000 mg film-coated tablets

SPC has been updated with addition of data regarding haemoglobin level on treatment.

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Midlands and Lancashire  
Commissioning Support Unit

### Zoton (lansoprazole) FasTab 15 mg

SPC now advises that hypomagnesaemia may lead to hypocalcaemia and/or hypokalaemia. In most affected patients, hypomagnesaemia (and hypomagnesaemia associated hypocalcaemia and/or hypokalaemia) improved after magnesium replacement and discontinuation of the PPI.

### 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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