

## Medicines Safety Assurance Tool

June 2020

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

### Cyproterone acetate: new advice to minimise risks of meningioma

29 June 2020

Risk of meningioma with cyproterone acetate increases with increasing cumulative dose

Proposed action

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



Action taken

Status

Unassigned ▼

Action due date

Date completed

### Direct-acting oral anticoagulants (DOACs): reminder of bleeding risk, including availability of reversal agents

29 June 2020

Remain vigilant for signs and symptoms of bleeding complications during treatment with DOACs (apixaban, dabigatran, edoxaban, rivaroxaban), especially in patients with increased bleeding risks.

Proposed action

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



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### Summary of Product Characteristics updates

#### [Constella \(linaclotide\) 290 micrograms hard capsules](#)

Urticaria has been added to SPC as an uncommon adverse reaction.

#### [Erythroped \(erythromycin ethylsuccinate\) SF 250mg/5ml](#)

SPC updated to warn erythromycin should not be given to patients with a history of QT prolongation (congenital or documented acquired QT prolongation) or ventricular cardiac arrhythmia, including torsades de pointes.

#### [Evra \(ethinylestradiol/norelgestromin\) transdermal patch](#)

Anaphylactic reaction has been added as a rare adverse event.

#### [GlucaGen \(glucagon\) Hypokit 1 mg](#)

The tip cap of the syringe included in the GlucaGen HypoKit no longer contains natural rubber latex.

#### [Kenalog \(triamcinolone acetonide\) Intra-articular/Intramuscular Injection](#)

Blurred vision has been added as adverse effect and SPC updated to advise that visual disturbance may be reported with systemic/topical corticosteroid use and if a patient presents with such symptoms, they should be considered for referral to an ophthalmologist for evaluation.

#### [Ovranette \(ethinylestradiol/ levonorgestrel\) tablets](#)

SPC contraindicates concomitant use with ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir & sofosbuvir/velpatasvir/voxilaprevir owing to significant increases in ALT levels, and warns that oestrogens may induce or exacerbate hereditary & acquired angioedema.

Proposed action

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### Rigevidon (ethinylestradiol, levonorgestrel) tablets

SPC updated to warn ethinylestradiol, levonorgestrel products are contraindicated for concomitant use with the medicinal products containing lecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir.

### Seroquel (quetiapine) tablets

SPC now details that in patients presenting with extensive rash, exfoliative dermatitis, fever, lymphadenopathy and eosinophilia, treatment should be withdrawn immediately as it may be suggestive of a severe cutaneous adverse reaction, such as Stevens-Johnson syndrome.

### Sevodyne (buprenorphine) transdermal patch – all strengths

SPC updated to warn that for all patients, prolonged use may lead to drug dependence, even at therapeutic doses; and risks are increased in individuals with current or past history of substance misuse disorder or mental health disorder.

### Solu-Medrone (methylprednisolone) 40 mg Powder for Injection

Cow's milk allergy has been removed from the list of contraindications, and from the special warnings and precautions for use section. The list of excipients has been updated, as has the in-use shelf-life and storage conditions of the reconstituted product.

### Tenoretic 100 mg/25 mg and Tenoret 50 mg/12.5 mg (atenolol/chlortalidone) film coated tablets

Choroidal effusion has been added to SPC as ADR of unknown frequency. It is noted that sulphonamide/sulfonamide derivative drugs (such as chlortalidone) can cause this idiosyncratic reaction which can lead to visual field defect, transient myopia and acute angle-closure glaucoma.

### ViePax (venlafaxine hydrochloride) XL prolonged-release tablets – all strengths

SPCs updated to include stress cardiomyopathy as an undesirable effect of treatment with unknown frequency.

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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### Xalacom eye drops, solution (timolol)

Hallucinations has been added as an adverse drug reaction.

### Zebinix (eslicarbazepine) 200mg tablets

SPC now advises that as bioavailability (AUC and Cmax) has been shown to be comparable with whole tablets, for patients who can't swallow, the tablets may be crushed and mixed with water or soft foods such as apple sauce immediately prior to administration.