

## Medicines Safety Assurance Tool

May 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

### [European Medicines Agency \(EMA\) review finds risks of Ingenol mebutate \(Picato\) for actinic keratosis outweigh benefits](#)

05 May 2020

Review compared Picato with imiquimod. After 3 years, 6.3% of patients treated with Picato (15/240) developed skin cancer, particularly squamous cell carcinoma, in the treated skin area vs. 2% of imiquimod patients (5/244 patients).

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

### [Yellow Card Reporting Site For Healthcare Products Used In Coronavirus \(Covid-19\)](#)

05 May 2020

The Medicines and Healthcare products Regulatory Agency (MHRA) has launched a dedicated Yellow Card reporting site for healthcare products that are used in Coronavirus (COVID-19) treatment to be easily reported: [coronavirus-yellowcard.mhra.gov.uk](https://coronavirus-yellowcard.mhra.gov.uk)

Proposed action

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

Action taken

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### [Chiesi release batch specific variation for Clenil 100 microgram inhaler owing to temporary increased demand](#)

06 May 2020

To address the current increased demand of Clenil Modulite 100mcg additional batches are to be released into the UK supply chain following authorisation by the MHRA for a batch-specific variation. The batches are beige and yellow (as opposed to brown and beige).

Proposed action

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

Action taken

Status

Unassigned ▼

Action due date

Date completed

### [PRAC concludes review of new information on the known risk of breast cancer with hormone replacement therapy](#)

15 May 2020

The European PRAC has recommended updating the current safety information for HRT, following new evidence confirming the known higher risk of breast cancer, and suggesting this may continue to be increased for at least 10 years after stopping, if it has been used for >5 years.

Proposed action

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 Practice audit/search  Other (please specify)

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### [Valproate Pregnancy Prevention Programme: temporary advice for management during coronavirus \(COVID-19\)](#)

22 May 2020

This Drug Safety Update discusses recent guidance issued for specialists to support adherence to the pregnancy prevention requirements for girls and women of childbearing potential taking valproate during the pandemic, particularly those shielding due to other health conditions.

Proposed action

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

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## Summary of Product Characteristics updates

### [Abilify \(aripiprazole\) – all products](#)

Photophobia has been added as a side effect of treatment of uncommon ( $\geq 1/1,000$  to  $< 1/100$ ) frequency.

### [Avelox \(moxifloxacin\) tablets](#)

Delirium (rare), pancytopenia, SIADH, hypoglycaemic coma (very rare), acute generalised exanthematous pustulosis and rhabdomyolysis (frequency unknown) have been added as potential adverse effects of treatment.

Proposed action

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### [Alimemazine Tartrate 7.5mg/5ml Syrup ftr](#)

The paediatric indications have been updated to include; pre-medication sedation before general anaesthesia in children aged 3-7 years and as a second-line treatment in the symptomatic relief of urticaria and pruritus in children aged 3 years and above.

### [Bexsero Meningococcal Group B vaccine for injection in pre-filled syringe](#)

SPC updated to include new dosing recommendations for primary immunisations in infants from 2 months of age. The dosing schedule is either 3 doses of 0.5 ml with an interval of not less than 1 month, or two doses of 0.5 ml with an interval of not less than two months.

### [Bisacodyl tabs](#)

SPC now highlights that bisacodyl 5mg tablets should not be used in children <12 years. Also warns against long-term everyday use of stimulant laxatives due to potential harm to the intestinal function.

### [Bonjela \(lidocaine/cetylpyridinium\) Junior Gel](#)

Infant teething pain indication has been removed and use restricted to age over 5 months, and addition of warning that excessive dosage, short intervals between doses or use on traumatised mucosa may result in high plasma levels and serious adverse effects.

### [Cipramil \(citalopram\) tablets](#)

SPC now highlights that sexual dysfunction reported with SSRIs/SNRIs may be long lasting despite treatment discontinuation. Also advises that owing to CYP2C19 inhibition by fluconazole, concomitant use should only be undertaken when necessary and with caution.

### [Diamicron \(gliclazide\) tablets – all products](#)

Autoimmune bullous disorders have been added as rare ( $\geq 1/10,000$  to  $< 1/1,000$ ) side effects of treatment.

### [Equasym XL \(methylphenidate\) Capsules](#)

SPC details data from use in pregnancy from a cohort study in 3,400 patients which found a small increased risk of congenital cardiac malformations. It advises that treatment is not recommended during pregnancy unless postponing treatment may pose a greater risk to the pregnancy.

### [Fasigyn \(tinidazole\) 500mg film-coated tablets](#)

SPC notes tinidazole is contraindicated in the first trimester of pregnancy. There is no evidence it is harmful during the latter stages, but it should only be used in the second and third trimesters where absolutely

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necessary. Animal data on fertility has been added.

### [Fycompa \(perampanel\) film-coated tablets – all strengths](#)

The SPC now includes a warning on the risk of Stevens-Johnson syndrome as a potential severe cutaneous adverse reaction (frequency not known).

### [MicardisPlus 80 mg/12.5 mg \(telmisartan/ hydrochlorothiazide\) tablets](#)

The eye disorder “choroidal effusion” has been added as an adverse event associated with use of hydrochlorothiazide.

### [Mirena \(levonorgestrel\) 20 micrograms/24 hours intrauterine delivery system](#)

The SPC has been updated to include ‘dizziness’ as a common side effect.

### [Singulair \(montelukast\) preparations](#)

SPC has been updated to state that data for use in pregnancy from case series did not establish a drug-associated risk, but that the studies have methodological limitations. SPC states that montelukast may be used during pregnancy only if it is considered to be clearly essential.

### [Targinact \(oxycodone/naloxone\) prolonged-release tablets- all strengths](#)

SPCs now warn that concomitant administration of oxycodone with serotonin agents, such as SSRIs or SNRIs may cause serotonin toxicity, and gabapentinoids have been added to list of potential interacting CNS depressant drugs.

### [Tetrabenazine 25 mg tablets](#)

Impaired hepatic function is now a contraindication to treatment with tetrabenazine

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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### Tildiem (diltiazem) Modified-Release tablets

SPC now details that cases of acute renal failure secondary to decreased renal perfusion have been reported in patients with reduced left ventricular function, severe bradycardia or severe hypotension.