

## Medicines Safety Assurance Tool

January 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)

### Sodium valproate Pregnancy Prevention Programme – updated Guide for Healthcare Professionals

17 Jan 2020

Changes include new sections titled “definition of specialist prescriber”, “contraception” and “does this apply to my patient”. The updated guide now also clarifies that provisions of prevent apply when a patient is switched from valproate to another treatment.

Proposed action

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

Action taken

Status

Unassigned

Action due date

Date completed

### European Medicines Agency (EMA) suspends Picato (ingenol mebutate) gel as a precaution while review of skin cancer risk continues

23 Jan 2020

Final results from a study comparing Picato with imiquimod indicate a higher occurrence of skin cancer in the treatment area with Picato than with imiquimod. EMA’s safety committee (PRAC) is currently reviewing data on skin cancer in patients using Picato.

Proposed action

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

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Midlands and Lancashire  
Commissioning Support Unit

### [PRAC confirms four-week limit for use of high-strength estradiol creams \(100 micrograms/gram \[0.01%\]\)](#)

23 Jan 2020

Following a re-examination procedure, the PRAC has confirmed its recommendation to minimise risk of side effects from absorption of high-strength estradiol creams into bloodstream, following intravaginal administration to treat symptoms of vaginal atrophy in post-menopausal women

Proposed action

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

Action taken

Status

Unassigned ▼

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Date completed

### [E-cigarette use or vaping: reporting suspected adverse reactions, including lung injury](#)

28 Jan 2020

Be vigilant for any suspected adverse reactions associated with use of e-cigarettes or vaping (including lung injury) and report them to the MHRA via the Yellow Card Scheme. In this article we provide UK case definitions of e-cigarette or vaping associated lung injury (EVALI) to facilitate identification.

Proposed action

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

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### Ondansetron: small increased risk of oral clefts following use in the first 12 weeks of pregnancy

28 Jan 2020

Recent epidemiological studies suggest exposure to ondansetron during the first trimester of pregnancy is associated with a small increased risk of the baby having a cleft lip and/or cleft palate.

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### Summary of Product Characteristics updates

January 2020

#### [Aldactide \(spironolactone and hydroflumethiazide\) – all strengths](#)

Basal cell carcinoma and squamous cell carcinoma have been added as undesirable effects of unknown frequency.

#### [Briviact \(brivaracetam\) Film-coated Tablets, oral solution and solution for injection/infusion](#)

The tablets contain lactose and section 4.4 warns patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine. The liquid and tablets are now considered sodium-free.

#### [Budenofalk \(budesonide\) 3mg gastro-resistant capsules](#)

The entire SPC has been updated as a result of a change in indication from collagenous colitis to microscopic colitis, with consequential changes to other sections.

#### [Celebrex \(celecoxib\) 100mg capsule](#)

Section 4.4 of the SPC now includes concomitant use of antiplatelet drugs as a risk factor for increased incidence for upper and lower gastrointestinal complications.

#### [Eltroxin \(Levothyroxine\) tablets- all strengths](#)

Wording as per PRAC recommendation has been included in SPC to advise that haemodynamic parameters should be monitored when levothyroxine is initiated in very low birth weight preterm neonates as circulatory collapse may occur due to immature adrenal function.

#### [Firmagon \(degarelix acetate\) 80 and 120mg Injection](#)

Rhabdomyolysis has been added to SPC as a rare adverse drug reaction.

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### Fluarix Tetra suspension for injection (influenza vaccine-split virion, inactivated) in pre-filled syringe

SPC has been updated to advise that Fluarix Tetra can be concomitantly administered with adjuvanted herpes zoster vaccine (Shingrix).

### Genticin (Gentamicin 0.3% w/v) eye/ear drops

SPC contraindications updated to include myasthenia gravis and perforation of the ear drum. Interactions with potent diuretics, amphotericin B, cisplatin, cyclosporin and cephalosporins added; due to increased risk of ototoxicity/nephrotoxicity.

### Ibuprofen gel – all products

SPCs revised to instruct patients not to smoke or go near naked flames due to risk of severe burns; and that fabric that has been in contact with these products burns more easily and is a serious fire hazard. Washing clothing and bedding recommended to reduce product build-up.

### Imodium (loperamide) - all products

SPCs have been revised to now state that overdose can unmask existing Brugada syndrome, an autosomal-dominant inherited arrhythmic disorder.

### Levitra (vardenafil) tablets (all strengths)

SPC has been updated to advise that serious CV events including sudden death, tachycardia, MI, ventricular tachy-arrhythmia, angina pectoris, and cerebrovascular disorders (including TIA and cerebral haemorrhage), have been reported in temporal association with vardenafil.

### Li-Liquid (lithium citrate) Oral Syrup

Lichenoid drug reaction has been added to the SPC as a potential adverse effect of treatment (frequency unknown).

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### Locoid (hydrocortisone butyrate) products

SPCs updated to instruct patients not to smoke or go near naked flames as fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing the fabric may reduce product build-up but not totally remove it.

### Lustral (sertraline) film coated tablets – all strengths

The entire SPC has been updated to detail caution for use in patients with risk factors for QTc prolongation such as cardiac disease, hypokalaemia or hypomagnesaemia, familial history of QTc prolongation, bradycardia and concomitant use of medications which prolong QTc interval.

### Lyrica (pregabalin) 20 mg/ml oral solution and hard capsules (all strengths)

Sections 4.4 and 4.5 of the SPC advises caution when used with opioids due to risk of CNS depression - this increased risk was observed at low doses of pregabalin ( $\leq 300$  mg) and there was a trend for a greater risk at high doses of pregabalin.

### Menveo (meningococcal) Group A,C,W135 and Y conjugate vaccine

Lymphadenopathy after vaccination (in the post marketing experience) has been added to SPC as a new expected adverse reaction.

### Nebido (testosterone undecanoate) 1000mg/4ml, solution for injection

SPC has been updated to advise that testosterone should be used with caution in patients with thrombophilia or risk factors for venous thromboembolism as there have been post-marketing studies and reports of thrombotic events in these patients during testosterone therapy.

### Nexplanon (etonogestrel) 68 mg implant for subdermal use

SPC updated to include post market surveillance reports of undesirable effects from treatment including; respiratory disorders (e.g. cough and haemoptysis) and haematoma following insertion or removal of the implant.

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### Nitrofurantoin 100 mg Tablets

SPC has been updated to highlight that nitrofurantoin should always be taken with food or milk. Taking Nitrofurantoin with a meal improves absorption and is important for optimal efficacy.

### Oxytetracycline tablets

SPC now advises that oxytetracycline may cause an increase in serum lithium levels when taken concomitantly with lithium-containing medications. The lithium dosage should either be adjusted or concomitant treatment stopped, as appropriate.

### Pradaxa (dabigatran) capsules

SPC now advises that concomitant administration with glecaprevir/pibrentasvir is contraindicated owing to increased risk of bleeding due to increased dabigatran levels. Also, alopecia has been added as a potential adverse effect of treatment (frequency unknown).

### Sodium valproate, valproate semi-sodium and valproic acid products

SPC now advises that in utero exposure to valproate may also result in hearing impairment or deafness in the child due to ear and/or nose malformations and/or to direct toxicity on the hearing function. When outcomes were reported, the majority of the cases did not recover.

### Sytron (sodium ferredetate trihydrate) 27.5 mg iron per 5 ml Oral Solution

SPC updated to state product contains 23 mg sodium in the recommended 10 ml dose for adults, which is 1.2% of the WHO recommended total daily intake of 2g; and contains 1400 mg sorbitol in 5 ml therefore patients with hereditary fructose intolerance should not take.

### Tetralysal (lymecycline) 300mg Hard Capsules

SPC revised to warn that concomitant use of lymecycline with lithium may cause an increase in serum lithium levels. This a recognised interaction of the tetracycline class.

### Tiopex (timolol) eye gel

Hallucination has been added to the SPC as a potential adverse effect of treatment (frequency not stated).

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### Tramacet 37.5 mg/ 325 mg (tramadol with paracetamol) film-coated tablets and effervescent tablets

Section 4.4 of the SPC advises “Opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxaemia (risk of CSA increased in dose-dependent fashion). In patients who present with CSA, consider decreasing the total opioid dosage.”

### Zydol (tramadol) all preparations

Section 4.4 of the SPC advises “Opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxaemia (risk of CSA increased in dose-dependent fashion). In patients who present with CSA, consider decreasing the total opioid dosage.”

## 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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