

Medicines Safety Assurance Tool

June 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



Midlands and Lancashire
Commissioning Support Unit

Letter to women and girls taking sodium valproate

15 June 2021

This letter has been sent to women and girls aged 12-55 who are currently prescribed sodium valproate and contains important reminders of safety considerations, including around contraception, pregnancy and regular prescribing reviews.

Proposed action

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



Action taken

Status	Action due date	Date completed

Public Assessment Report: safety of macrolide antibiotics in pregnancy: a review of the epidemiological evidence

28 June 2021

The overarching findings of this review are that the available evidence is insufficient to confirm with certainty the presence or absence of a small increased risk of malformations or miscarriage when macrolides are taken in early pregnancy.

Proposed action

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



Action taken

Status	Action due date	Date completed

Medicines Safety Assurance Tool

June 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



Midlands and Lancashire
Commissioning Support Unit

Summary of Product Characteristics updates

Arimidex (anastrozole) 1mg Film-Coated Tablet

SPC updated with addition of depression as very common adverse drug reaction

Butec (buprenorphine) transdermal patch-all strengths

Warnings have been added to SPC regarding potential skin reactions and hot water bottles have been added to list of sources of heat that it is recommended to avoid.

Constella (linaclotide) 290 micrograms hard capsules

Cases of intestinal (IN) perforation have been reported after use of linaclotide in patients with conditions that may be linked to localised/diffuse IN wall weakness. Immediate medical care should be sought in case of severe, persistent, or worsening abdo pain & treatment stopped.

Dailiport and Adoport (tacrolimus) – all presentations

SPC now warns co-administration with metamizole, an inducer of metabolising enzymes including CYP2B6 and CYP3A4 may cause a reduction in plasma levels of tacrolimus with potential decrease in clinical efficacy. (metamizole [Nolotil] is an analgesic that is not available in UK).

Entresto (sacubitril/valsartan) film-coated tablets- all strengths

SPC now advises splitting or crushing of tablets is not recommended and clarifies increases in serum lithium have been reported during concomitant administration with lithium. Psychiatric disorders including hallucinations, paranoia & sleep disorders have been added as rare ADRs.

Proposed action

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



Action taken

Status

Action due date

Date completed

Medicines Safety Assurance Tool

June 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



Midlands and Lancashire
Commissioning Support Unit

Epilim (sodium valproate) – all presentations

SPC now notes that although the safety profile in paediatrics is comparable to adults, based on a limited number of post-marketing cases, Fanconi Syndrome, enuresis and gingival hyperplasia have been reported more frequently in paediatric patients than in adult patients.

Ethinylestradiol/gestodene (Femodette, Femodene) and cyproterone acetate/ethinylestradiol (Dianette) tablets

SPCs have been updated to include wording on a potential drug-drug interaction of ethinylestradiol containing products with Maviret (glecaprevir/pibrentasvir) leading to risk of ALT elevations.

Etrivex (clobetasol) 500 micrograms/g Shampoo

SPC warns of cases of osteonecrosis serious infections and systemic immunosuppression with long-term use beyond recommended doses and advises if treatment with local corticosteroids is required beyond 4 weeks, a less potent corticosteroid preparation should be considered.

Frisium (clobazam) 10mg Tablets

SPC updated to warn that co-administration of cannabidiol with clobazam can elevate levels of N-desmethyloclobazam which may lead to increased ADR (somnolence and sedation), likely mediated by CYP2C19 inhibition. Dosage adjustment of clobazam may be necessary.

Indocid (indomethacin) Suppositories 100 mg

SPC now highlights that studies in premature neonates being treated for patent ductus arteriosus have shown that concomitant administration of indometacin and vancomycin may have additive nephrotoxic effects, as indometacin may increase the risk of vancomycin related toxicities.

Medicines Safety Assurance Tool

June 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



Midlands and Lancashire
Commissioning Support Unit

Influvac sub-unit Tetra and Tetra MYL (quadrivalent influenza vaccines)

SPCs updated to include a new paediatric indication in children aged 6 – 35 months of age. The use of Influvac sub-unit Tetra should be based on official recommendations.

Instanyl (fentanyl citrate) nasal spray, solution in single-dose container

SPC updated to note opioids can cause sleep-related breathing disorders including central sleep apnoea and sleep-related hypoxaemia. Overdose symptoms have also been updated to note that cases of Cheyne Strokes respiration have been observed in cases of fentanyl overdose.

Mysimba 8 mg/90 mg (naltrexone hydrochloride/bupropion hydrochloride) prolonged-release tablets

SPC warns that co-administration of naltrexone/bupropion with digoxin may decrease plasma digoxin levels. Therefore monitor digoxin levels and signs of toxicity on stopping. Furthermore lupus erythematosus has been added as possible adverse reaction of unknown frequency.

Palexia (tapentadol) products

SPC now warns long-term maternal use of opioids during pregnancy may lead to newborn experiencing subsequent neonatal withdrawal syndrome which can be life-threatening if not recognized & treated; antidote should be readily available. It also notes lack of human data on fertility.

Qutenza (capsaicin) 179mg cutaneous patch

SPC has been revised to reiterate protective measures to be taken when applying Qutenza & provide more precise guidance on measures to be taken when capsaicin comes in contact with eyes/mucous membranes and on course of action if respiratory irritation worsens or does not resolve.

Medicines Safety Assurance Tool

June 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

Midlands and Lancashire
Commissioning Support Unit

Rebrikel (buprenorphine) transdermal patches – all strengths

SPC updated to include caution for sleep-related breathing disorders including sleep-related hypoxemia and central sleep apnoea (CSA) with recommendation to decrease total opioid dosage in patients who present with CSA and application skin discolouration added as side effect.

Tenormin (atenolol) – all formulations

SPC notes addition of depression as an adverse drug reaction (frequency unknown).

Trulicity (dulaglutide) solution for injection in pre-filled pen

Delayed gastric emptying has been added as a rare potential adverse effect of treatment.

Zyban (bupropion hydrochloride) 150 mg prolonged release tablets

SPC updated to include aggravation of Systemic lupus erythematosus syndrome and cutaneous lupus erythematosus as undesirable effects of unknown frequency.

Zydol (tramadol) XL 400 mg prolonged-release Tablets

Section on adrenal insufficiency (AI) has been amended to advise that opioid analgesics may occasionally cause reversible AI requiring monitoring and glucocorticoid replacement therapy. Symptoms of acute or chronic adrenal insufficiency are described.