

Medicines Safety Assurance Tool

January 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

SSRI/SNRI antidepressant medicines: small increased risk of postpartum haemorrhage when used in the month before delivery

07 January 2021

Data from observational studies suggest use of SSRI/SNRI antidepressants during month before delivery may result in small increased risk of postpartum haemorrhage. Prescribers should consider this risk vs. benefits of antidepressants for patient's mental health during this time.

Proposed action

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



Action taken

Status

Action due date

Date completed

Use of medicines in pregnancy and breastfeeding

13 January 2021

This guidance signposts patients, healthcare professionals and developers of new medicines to advice and resources on medicines in pregnancy and breastfeeding and is supported by Safer Medicines in Pregnancy and Breastfeeding Consortium.

Proposed action

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



Action taken

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Valproate use by women and girls

13 January 2021

New versions of the patient card, patient booklet, and healthcare professionals booklet (dated November 2020) are now available.

Proposed action

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



Action taken

Status

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Summary of Product Characteristics updates

Asacol (mesalazine) preparations

SPC now notes that severe cutaneous adverse reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported with mesalazine (frequency unknown). It should be discontinued, at the first appearance of signs and symptoms of severe skin reactions.

Betnesol-N (neomycin sulfate betamethasone sodium phosphate) Eye, Ear and Nose Drops

SPC highlights warnings of increased risk of ototoxicity with aminoglycosides administered to pts with mitochondrial mutations, particularly the m.1555A>G mutation, including cases where aminoglycoside levels were within recommended range. The incidence of this effect is unknown.

Proposed action

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



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Cipramil (citalopram) 20 mg film-coated tablets

SPC now includes warning that SSRIs/SNRIs may increase the risk of postpartum haemorrhage (observational data indicate an increased risk, less than 2-fold, following exposure within the month prior to birth).

Cortiment (budesonide) prolonged release tablets

SPC now provides details for use in the new indication of induction of remission in active microscopic colitis. The recommended schedule is 1 tablet (9 mg) daily for up to 8 weeks.

Depakote and Epilim (valproic acid and sodium valproate) products

SPC now notes that although the safety profile in paediatrics is comparable to adults, some reactions are more severe or principally observed in children, e.g. particular increased risk of severe liver damage, pancreatitis, and psychiatric disorders (e.g. aggression).

Equasym (methylphenidate) XL 0 mg Capsules- all strengths

Dysphemia (stuttering) has been added to SPC as an adverse effect of unknown frequency.

Innovace (enalapril) Tablets- all strengths

SPC now advises that patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take Innovace tablets.

Lamictal (lamotrigine) tablets and dispersible tablets

SPC updated to include warning on photosensitivity (frequency uncommon). In several cases, the reaction occurred with a high dose upon dose escalation or rapid up-titration. If treatment required, advise pt to avoid exposure to sunlight/UV light and take protective measures.

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[Lixiana \(edoxaban\) Film-Coated Tablets – all strengths](#)

SPC advises that for patients unable to swallow, tablets may be crushed and mixed with water/apple puree and immediately administered. Alternatively, tablets may be crushed and suspended in water and immediately delivered through a gastric tube followed by flushing with water.

[Madopar CR 100 mg/25 mg \(benserazide hydrochloride, levodopa\) Prolonged Release Hard Capsules](#)

SPC updated to note that the capsules contain soya oil, therefore it is contraindicated in patients allergic to peanut or soya.

[Medikinet \(methylphenidate hydrochloride\) XL modified-release capsules, hard – all strengths](#)

SPCs updated to include the following undesirable effects; dysphemia (a nervous system disorder) and trismus (a musculoskeletal and connective tissue disorder) of unknown frequency.

[Mezavant XL \(mesalazine\) 1200mg, gastro-resistant, prolonged release tablets](#)

SPC updated to include hepatotoxicity as an adverse event (unknown frequency).

[Minims Cyclopentolate Hydrochloride 0.5%, Eye drops solution](#)

Seizures, necrotising colitis, anaphylactic reaction/shock have been added to SPC as adverse effects.

[NiQuitin \(nicotine\) Pre-Quit Clear 21mg Patch](#)

SPC updated to emphasise requirement for safe disposal; nicotine doses tolerated by adult & adolescent smokers can produce severe toxicity in children. Pre-cessation regimen should not be used in people with known CVD without evaluation of risk/benefit by healthcare professional.

[Piriton \(chlorphenamine\) preparations](#)

SPC now notes a minimum dosing interval of 4 hours and states not to use for longer than 2 weeks without consulting a doctor, and to avoid use in elderly patients with confusion. Medical advice should be sought before using with other drugs that cause sedation.

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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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Midlands and Lancashire
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Zocor (simvastatin) film-coated tablets- all strengths

SPC does not recommend concomitant use of ticagrelor with doses of simvastatin greater than 40 mg due to increases in serum concentration of simvastatin, with a 2-to 3-fold increase in some individuals.