

## Medicines Safety Assurance Tool

March 2022

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)

### Potential Contamination Of Alimentum And Elecare Infant Formula Food Products

04 March 2022

The recall notice provides product details and specific batch codes which may have possible contamination with Salmonella Newport and Cronobacter sakazakii. They must not be used, patients supplied these products should be contacted and products should be returned to a pharmacy.

Proposed action

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



Action taken

Status	Action due date	Date completed

### Amiodarone (Cordarone X): reminder of risks of treatment and need for patient monitoring and supervision

15 March 2022

Amiodarone has been associated with serious and potentially life-threatening side effects, particularly of the lung, liver, and thyroid gland. We remind healthcare professionals that patients should be supervised and reviewed regularly during treatment.

Proposed action

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



Action taken

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### Metformin in pregnancy: study shows no safety concerns

15 March 2022

A large study has shown no safety issues of concern relating to the use of metformin during pregnancy. The licence for metformin now reflects that it can be considered for use during pregnancy and the periconceptional phase as an addition or an alternative to insulin, if clinically needed. This is consistent with current clinical guidance.

Proposed action

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



Action taken

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## Summary of Product Characteristics updates

### Advagraf (tacrolimus) preparations

SPC now notes weak CYP3A4 inducers such as flucloxacillin may decrease tacrolimus levels. Also notes that where concurrent use with nephrotoxic drugs cannot be avoided tacrolimus levels and renal function should be monitored closely.

### Camcolit 400 mg, controlled release Lithium Carbonate

SPC updated to warn that co-administration with empagliflozin may lead to decreased lithium concentrations and a risk of loss of efficacy.

Proposed action

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



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### Cellcept (mycophenolate mofetil)-all products

Recommendation to consider dose reduction or discontinuation of treatment for patients in cases of clinically significant COVID-19 has been removed.

### Cordarone X (amiodarone) 200 mg Tablets

The part of section 4.4 discussing lung toxicity updated to state that as initial radiological changes may be difficult to distinguish from pulmonary venous congestion, high-definition computerised tomography scans may be more useful than chest X-rays in confirming a diagnosis.

### Co-Diovan (valsartan/hydrochlorothiazide) Tablets- all strengths

SPC updated to warn very rare severe cases of acute respiratory toxicity, including acute respiratory distress syndrome have been reported after taking hydrochlorothiazide. Pulmonary oedema typically develops within minutes to hours after hydrochlorothiazide intake

### Elidel (pimecrolimus) 10 mg/g Cream

Updated with addition of infant indication (covering treatment of patients 3 months of age and older with mild or moderate atopic dermatitis where treatment with topical corticosteroids is either inadvisable or not possible) and related clinical data.

### Glucophage (metformin) film coated tablets

SPC updated to include warning that metformin may reduce vitamin B12 levels (common adverse event). Risk increases with increasing dose, treatment duration, and/or in pts with risk factors for vitamin B12 deficiency. Monitoring is recommended with appropriate corrective treatment.

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### [Glyxambi 10mg/5mg and 25mg/5mg \(empagliflozin/linagliptin\) Film-coated Tablets](#)

SPC updated with section on CKD; the section on renal impairment revised to include table on dose adjustment recommendations, & section on CV safety now includes information about effect of empagliflozin on primary combined endpoint of CV death, non-fatal MI & non-fatal stroke.

### [Ikervis \(ciclosporin\) 1 mg/mL eye drops, emulsion](#)

Updated to advise that after opening of aluminium pouches, the single-dose containers should be kept in pouches in order to protect from light & avoid evaporation. Any opened individual single-dose container with any remaining emulsion should be discarded immediately after use.

### [Indivina \(estradiol valerate/medroxyprogesterone acetate\) tablets- all strengths](#)

SPC updated to advise caution when co-administered with the combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir and also the regimen glecaprevir/pibrentasvir, due to indirect concerns about risk of ALT elevations in patients with hep C infections.

### [Labetalol Film-coated Tablets – all strengths](#)

SPC updated to include adverse event of nipple pain and Raynaud's phenomenon of the nipple, both of unknown frequency.

### [Lamictal \(lamotrigine\)- all products](#)

SPC notes at therapeutic doses up to 400 mg/day, lamotrigine did not slow ventricular conduction or cause QT prolongation in healthy individuals in a QT study, but use should be carefully considered in patients with clinically important structural or functional heart disease.

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### [Lyrica \(pregabalin\) hard capsules](#)

Section 4.6 has been updated concerning risks of pregabalin treatment during pregnancy. In addition, section 4.4 has been updated to highlight that pregabalin should not be used during pregnancy unless the benefit to the mother clearly outweighs the potential risk to the foetus.

### [Methotrexate 2mg/ml Oral Solution \(Rosemont\)](#)

Prescriber's guide aims to mitigate potential risk of medication errors in patients treated for arthritis/psoriasis in a weekly regimen. It also provides guidance for preparing dosages for children >3 years, adolescents and adults being treated for acute lymphoblastic leukaemia.

### [Nexium \(esomeprazole\) formulations](#)

The adverse reactions table has been updated to include Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), and further information relating to serious cutaneous adverse reactions has been added to section 4.4.

### [Nimenrix \(meningococcal groups A, C, W-135 and Y conjugate vaccine\) powder and solvent for solution for injection in pre-filled syringe](#)

Febrile convulsion (rare) and urticaria (uncommon) have been added to SPC as new adverse drug reactions.

### [Olmesartan containing products](#)

Autoimmune hepatitis has been added as a potential adverse effect of olmesartan treatment (unknown frequency).

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### Skudexa (tramadol hydrochloride, dexketoprofen) tablets and Keral (dexketoprofen) tablets

SPCs warn that dexketoprofen can mask symptoms of infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. SPC advises to monitor for infection and avoid use of dexketoprofen in case of varicella.

### Syonell (valproate semisodium) Gastro-Resistant Tablets

SPC notes that the initial recommended daily dose is 750 mg in 2-3 divided doses. It adds that in patients on haemodialysis it may be necessary to increase or decrease the dosage according to clinical monitoring of the patient.

### Topamax (topiramate)- all presentations

SPC updated with data from 1-year, open-label study in paediatric patients aged 6 to 15 years including 63 subjects with recent or new onset of epilepsy which suggest growth-related changes were not clinically significant nor treatment limiting.

### Vaxelis (diphtheria, tetanus and pertussis/poliomyelitis/ haemophilus influenzae type b/hepatitis b vaccine) for injection in pre-filled syringe

Convulsions with/without fever & hypotonic-hyporesponsive episode (frequency unknown) have been reported during post-marketing use. Hypersensitivity/anaphylactic reaction reported with other vaccines containing components of Vaxelis also added as ADR without regard to causality.

### Zomig (zolmitriptan) Tablets 2.5mg

The storage conditions have been changed from “Do not store above 30°C” to “Do not store above 25°C”.

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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### Zydol (tramadol) XL prolonged-release Tablets

Hyperalgesia (increased sensitivity to pain) has been added as an undesirable effect.

## 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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