

Medicines Safety Assurance Tool

August 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

Nebulised asthma rescue therapy in children: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists

23 August 2022

Warning issued about nebuliser purchased independently of medical advice for use in home to deliver asthma rescue medications to children can mask deterioration in underlying disease & increase risk of potentially fatal delays in seeking medical attention if asthma deteriorates.

Proposed action

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



Action taken

Status	Action due date	Date completed

Risk Minimisation Materials updates

Amiodarone Patient Alert Card

This card outlines key safety information for patients taking amiodarone including signs and symptoms of amiodarone-induced lung damage, liver damage, worsening cardiac arrhythmias and thyroid problems.

Proposed action

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



Action taken

Status	Action due date	Date completed

Medicines Safety Assurance Tool

August 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

Summary of Product Characteristics updates

Alvedon (paracetamol) Suppositories

SPC notes increased risk of high anion gap metabolic acidosis when used with flucloxacillin, particularly in severe renal impairment, sepsis, malnutrition & other sources of glutathione deficiency. Close monitoring, including measurement of urinary 5-oxoproline is recommended.

Comirnaty Covid-19 vaccine

SPC updated to include information about receiving a heterologous booster dose in adults. The shelf life and transportation storage time information has been updated in the SPC for the purple cap product (Comirnaty 30 micrograms/dose concentrate for dispersion for injection).

Evorel patch (estradiol)

Various sections of SPC updated to clarify the text on the relationship between taking estradiol as HRT and the risk of developing breast cancer.

Fentanyl (Effentora) 600 mcg Buccal Tablets

The section on interaction with agents that can increase CNS depressant effects has been updated to include gabapentinoids (gabapentin and pregabalin) and to include the possible outcomes of respiratory depression, hypotension, profound sedation and coma.

Glyxambi (empagliflozin/linagliptin) Film-coated Tablets- all strengths

Updated to warn empagliflozin may increase renal lithium excretion and decrease levels, thus serum concentration of lithium should be monitored more frequently after empagliflozin initiation and dose changes. Tubulointerstitial nephritis added as a very rare adverse event.

Lemsip products containing paracetamol

Caution advised if paracetamol administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis, particularly in patients with severe renal impairment, sepsis, malnutrition, as well as those on maximum daily doses of paracetamol.

Proposed action

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



Action taken

Status

Action due date

Date completed

Medicines Safety Assurance Tool

August 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



Midlands and Lancashire
Commissioning Support Unit

Levosert (levonorgestrel) 20 micrograms/24 hours Intrauterine Delivery System

SPC warns risk of expulsion is increased in women with history of heavy menstrual bleeding & with greater than normal BMI at time of insertion, the risk of which increases gradually with increasing BMI. A partially expelled Levosert may decrease effectiveness & should be removed.

Lyrica (pregabalin) hard capsules

SPC updated to note cases of suicidal ideation and behaviour have been observed in patients treated with pregabalin. Patients should be monitored for signs of suicidal ideation and behaviour and treatment discontinuation considered if they emerge.

Methadone – all formulations and strengths

SPC updated in line with PRAC recommendations noting interaction between methadone and metamizole, an analgesic not available in UK, may cause a reduction in plasma concentrations of methadone with potential decrease in clinical efficacy, therefore caution and monitoring advised.

Nexplanon (etonogestrel) 68 mg implant for subdermal use

SPC now warns that insertion of the implant may cause vasovagal reactions (such as hypotension, dizziness, or syncope).

Nu-Seals cardio (acetylsalicylic acid) 75 Gastro-resistant Tablets

SPC updated to include benzyl alcohol (0.128mg per tablet) as an excipient with known effect & corresponding warning to use high volumes in caution & only if necessary, especially in patients with liver/kidney impairment due to risk of accumulation & toxicity (metabolic acidosis).

Pradaxa (dabigatran etexilate mesilate) hard capsules – all strengths

SPC updated to include warning of anticoagulant-related nephropathy in patients with predisposing risk factors under bleeding reactions section.

Pseudoephedrine (Galpseud) linctus

Ischaemic optic neuropathy has been added to the list of undesirable effects associated with this medicine.

Medicines Safety Assurance Tool

August 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

Quadrivalent Influenza Vaccine (split virion, inactivated), suspension for injection in pre-filled syringe

SPC now notes data from study of concomitant administration with COVID-19 mRNA vaccine which found no change to influenza vaccine immune responses as measured by hemagglutination inhibitor assay and similar responses to COVID-19 mRNA vaccine as assessed by an anti-spike IgG assay

Quinoric (hydroxychloroquine) 200mg Film-Coated Tablets

SPC warns cases of severe cutaneous adverse drug reactions, which may be life-threatening/ fatal, including drug reaction with eosinophilia and systemic symptoms, acute generalized exanthematous pustulosis, Stevens-Johnson syndrome & toxic epidermal necrolysis, have been reported

Voltarol (diclofenac sodium) 140mg Medicated Plaster

Updated to warn NSAIDs may interact with BP lowering drugs & may possibly enhance effects of anticoagulants, although these risks with use of topical preparation is extremely remote. Also now warns concurrent aspirin/other NSAIDs may result in increased incidence of ADRs.

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.

© NICE 2022. All rights reserved. Subject to [Notice of rights](#).

NICE guidance is prepared for the National Health Service in England. All NICE guidance is subject to regular review and may be updated or withdrawn. NICE accepts no responsibility for the use of its content in this product/publication.