Medicines Safety Assurance Tool

December 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

NHS Midlands and Lancashire Commissioning Support Unit

MHRA consultation with healthcare professionals (HCPs) on their safety communications

01 December 2022

MHRA is reviewing its approach to engagement on safety of medicines & medical devices. Its consultation is enabling HCPs across UK to have their say on how they wish to receive vital safety information, how they'd like to be engaged & to feedback on Yellow Card system.

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status	Action due date	Date completed

PRAC recommends withdrawal of pholcodine medicines from EU market

05 December 2022

Data found use of pholcodine within 12 months of general anaesthesia is a risk factor for developing an anaphylactic reaction to neuromuscular blocking agents. As it was not possible to identify measures to minimise the risk, the market authorisation is being withdrawn in the EU.

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status	Action due date	Date completed

Valproate: reminder of current Pregnancy Prevention Programme requirements; information on new safety measures to be introduced in the coming months

12 December 2022

In view of data showing ongoing exposure to valproate in pregnancy, this alert reminds HCPs of the risks in pregnancy, current Pregnancy Prevention Programme requirements and the new safety measures being put into place in the coming months following advice from CHM.

Proposed action

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

Action taken

Status | Action due date | Date completed

Assessing the impact of renal impairment on medicines safety in adults

19 December 2022

This article, part of a series on renal impairment and supported by information resources, provides advice on the considerations needed to assess renal function and ensure the safe use of medicines in the context of preserving kidney function.

Proposed action

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

Action taken

Status | Action due date | Date completed

Summary of Product Characteristics updates

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status | Action due date | Date completed

Lipitor (atorvastatin) 10 and 20 mg chewable tablets

Immune-mediated necrotizing myopathy has been added to SPC as an adverse drug reaction and ledipasvir/sofosbuvir added to list of antivirals for treatment of hepatitis C that may increase risk of myopathy with concomitant use with atorvastatin.

Lyrica (pregabalin) hard capsules- all strenghts

Toxic epidermal necrolysis has been added to SPC as a rare adverse effect.

Phenergan (promethazine)- all presentations

Updated to warn phenothiazine derivatives, of which promethazine is one, may potentiate QT prolongation (QTP), increasing risk of serious ventricular arrhythmias of torsade de pointes type. Special caution required when used concurrently with drugs known to cause QTP.

Zoton (lansoprazole) Fas Tab 15mg and 30mg

SPC updated with information warning about acute tubulointerstitial nephritis, which has been observed in patients taking lansoprazole and may occur at any point during treatment, and can progress to renal failure.

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