

## Medicines Safety Assurance Tool

March 2023

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)

### Pholcodine-containing cough and cold medicines: withdrawal from UK market as a precautionary measure

14 March 2023

Advice for healthcare professionals regarding the withdrawal of pholcodine-containing medicines from the market.

Proposed action

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



Action taken

Status

Action due date

Date completed

### Management of National Patient Safety Alerts

23 March 2023

This document describing the process for the management of National Patient Safety Alerts, has been designed in conjunction with patient safety specialists, patient safety partners, and alert originators.

Proposed action

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



Action taken

Status

Action due date

Date completed

## Medicines Safety Assurance Tool

March 2023

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)



Midlands and Lancashire  
Commissioning Support Unit

### Summary of Product Characteristics updates

#### [Aceclofenac tablets](#)

SPC notes, from 20th week of pregnancy, aceclofenac use may cause oligohydramnios resulting from foetal renal dysfunction & there have also been reports of ductus arteriosus constriction. Thus it should not be given, unless clinically indicated, during 1st & 2nd trimester.

#### [Briviact \(brivaracetam\) – all products](#)

SPC updated to advise that brivaracetam is excreted in human milk and that there is limited clinical data on use in neonates, with safety information currently available for 6 in this age group.

#### [Daktarin \(miconazole\) Aktiv Spray Powder](#)

Updated to advise that it contains 255 mg (10% w/w) ethanol in each gram of powder and may cause burning sensation on damaged skin.

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

Updated to include the potential to cause red-brown urine discoloration after contact with sodium hypochlorite bleach (e.g. in toilets cleaned with sodium hypochlorite contained in certain bleaches).

#### [Naproxen Orion 25 mg/ml oral suspension](#)

Updated to note that from the 20th week of pregnancy onward, naproxen use may cause oligohydramnios resulting from foetal renal dysfunction. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester.

#### [Oruvail \(Ketoprofen\) – all products](#)

SPC updated to advise risk of oligohydramnios resulting from foetal renal dysfunction from 20th week of pregnancy onward (reversible upon discontinuation) and reports of ductus arteriosus constriction after treatment in second trimester, mostly resolved after treatment cessation.

Proposed action

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



Action taken

Status

Action due date

Date completed

## Medicines Safety Assurance Tool

March 2023

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)



Midlands and Lancashire  
Commissioning Support Unit

### [Progynova \(estradiol\) preparations](#)

SPC now notes that for women with impaired liver function, close supervision is needed and in case of deterioration of markers of liver function, use of HRT should be stopped. Treatment is contra-indicated in patients with severe hepatic disease.

### [Promixin \(colistimethate sodium\) 1 million International Units \(IU\) Powder for Nebuliser Solution](#)

Updated to note there are no data on its effects on human fertility. Animal studies do not indicate adverse effects on fertility or embryo-foetal development. Non-clinical data reveal no hazard for humans based on studies of repeated dose toxicity and genotoxicity.

### [Slozem \(Diltiazem\) – all products](#)

Updated to advise careful monitoring of diabetic patients due to possible increase in blood glucose & to warn of risk of inducing bronchospasm, including asthma aggravation. Drug interaction section also updated, & warning added about increased drug exposure with grapefruit juice.

### [Symbicort Turbohaler 200/6 \(budesonide/formoterol\) Inhalation powder](#)

SPC updated with licence extension to reflect use as reliever therapy for adults and adolescents (12 years and older) with mild asthma.

### [Trelegy Ellipta \(fluticasone, vilanterol, umeclidinium\) 92 micrograms/55 micrograms/22 micrograms inhalation powder, pre-dispensed](#)

SPC updated with urinary retention and dysuria as rare adverse drug reactions.

### [Venladex \(venlafaxine\) XL 75 mg prolonged-release tablets](#)

Overdose section of the SPC updated to note severe poisoning symptoms may occur in adults after intake of approximately 3 grams of venlafaxine. Severe poisoning may require complex emergency treatment and monitoring.

## Medicines Safety Assurance Tool

March 2023

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)



Midlands and Lancashire  
Commissioning Support Unit

### [Venlafaxine XL 150 mg prolonged-release tablets \(Dexcel Pharma\)](#)

SPC now notes patients should be advised not to use alcohol, considering its CNS effects and potential of clinical worsening of psychiatric conditions, and potential for adverse interactions with venlafaxine.

Overdose with venlafaxine has been reported predominantly with alcohol.

### [Zyban \(bupropion\) 150 mg prolonged release tablets](#)

Bupropion may unmask Brugada syndrome, a rare hereditary disease of cardiac sodium channel with specific ECG changes (ST segment elevation & T wave abnormalities in right precordial leads), which may lead to cardiac arrest and/or sudden death. Caution advised in at risk patients.

## 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 2023. 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.