

Medicines Safety Assurance Tool

November 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

BNF and BNF for Children

Methylphenidate hydrochloride long-acting (modified-release) preparations: caution if switching between products due to differences in formulations [MHRA/CHM advice].

Nebulised asthma rescue therapy in children: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists [MHRA/CHM advice] (advice in ipratropium bromide, salbutamol, terbutaline sulfate; see example in **ipratropium bromide**).

Buprenorphine [update to indications and dose for transdermal patches].

BNF and BNF for Children Significant changes

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

Abstral (fentanyl) sublingual tablets- all strengths

Gabapentinoids (gabapentin and pregabalin) have been added to list of concomitant CNS depressants which may produce increased risk of sedation, respiratory depression, hypotension, coma and death because of additive CNS depressant effect.

Adipine XL (nifedipine) 30 mg Prolonged Release Tablets

The following psychiatric disorders have been added as undesirable effects: anxiety reactions (uncommon), sleep disorders (uncommon), mood changes (rare), and depression (not known).

Proposed action

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

Action taken

Status Action due date Date completed

Medicines Safety Assurance Tool

November 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

Asacol (mesalazine) 800mg MR Tablets

SPC updated with addition of interstitial nephritis & nephrotic syndrome as adverse effects of unknown frequency and drug fever (rare). It now notes reports of severe cutaneous adverse reactions and warning of nephrolithiasis, recommending adequate fluid intake during treatment.

Benylin and Sudafed products containing paracetamol

SPCs highlight interaction of paracetamol with flucloxacillin. Caution should be taken with concomitant use due to increased risk of high anion gap metabolic acidosis particularly in patients with severe renal impairment, sepsis, malnutrition and chronic alcoholism.

Brilique (ticagrelor) Tablets

SPC now notes that central sleep apnoea including Cheyne-Stokes respiration has been reported in the post-marketing setting in patients taking ticagrelor. If central sleep apnoea is suspected, further clinical assessment should be considered.

Ceyesto (melatonin) 3 mg tablets

SPC revised to reflect licence extension covering use in insomnia in children and adolescents aged 6-17 years with ADHD, where sleep hygiene measures have been insufficient.

Cipramil (citalopram) Drops 40 mg/ml

List of medicinal products with serotonergic effects that citalopram should not be used concomitantly with due to risk of serotonin syndrome has been updated to include oxitriptan opioids (including tramadol and buprenorphine).

Deximune (ciclosporin) 50 mg soft capsules

SPC updated to note hearing impairment has been reported in the post-marketing phase in patients with high levels of ciclosporin.

Medicines Safety Assurance Tool

November 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

[Dianette \(cyproterone/ ethinylestradiol\)](#)

Sofosbuvir, velpatasvir and voxilaprevir added to list of medicines contraindicated due to ALT elevations observed with concomitant use of ethinylestradiol-containing medications such as combined hormonal contraceptives.

[Diflucan \(fluconazole\) preparations](#)

SPC now highlights fluconazole can increase exposure to abrocitinib when taken concomitantly owing to enzyme inhibition. The dose should be adjusted as per the instructions in the abrocitinib prescribing information.

[Elvanse \(lisdexamfetamine dimesylate\) Hard Capsules – all strengths](#)

SPC updated to include warning that lisdexamfetamine crosses placenta; undesirable effects section updated with data on weight from RCT in children ages 4 to 5 years, and pharmacodynamic & pharmacokinetic section also updated with data from studies in children ages 4 to 5 years.

[Femodene \(gestodene/ ethinylestradiol\) tablets](#)

Sofosbuvir, velpatasvir and voxilaprevir added to list of medicines contraindicated due to ALT elevations observed with concomitant use of ethinylestradiol-containing medications such as combined hormonal contraceptives.

[Femodene ED tablets](#)

List of medicines for which concomitant use is contraindicated has been updated to include sofosbuvir/velpatasvir/voxilaprevir, as ALT elevations were observed in trials with patients treated for hepatitis C virus infection in women using ethinylestradiol-containing medicines.

[Firmagon \(degarelix\) 80 and 120mg Injection](#)

SPC updated with licence extension covering treatment of high-risk localised and locally advanced hormone dependent prostate cancer in combination with radiotherapy and also neo-adjuvant treatment prior to radiotherapy in this population.

Medicines Safety Assurance Tool

November 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

Levetiracetam preparations

SPC now includes neuroleptic malignant syndrome as a potential adverse effect of treatment (frequency unknown).

Losartan (Cozaar and Cozaar-Comp) Film-Coated Tablets - all strengths

SPC now warns grapefruit juice contains components that inhibit CYP450 enzymes and may lower concentration of active metabolite of losartan which may reduce therapeutic effect, therefore concomitant consumption of grapefruit juice should be avoided.

Mezavant XL (mesalazine) 1200mg, gastro-resistant, prolonged release tablets

The information on renal monitoring has been updated to clarify frequency of monitoring should be based on clinical judgement taking into account baseline renal function, and to note that treatment should be discontinued if renal function deteriorates.

Mysimba (naltrexone 8mg / bupropion 90 mg) prolonged-release tablets

SPC now notes that panic attacks have been reported with naltrexone/bupropion. The cases occurred mostly during the initial titration phase and following dose changes. Naltrexone/bupropion should be used with caution in patients with a history of psychiatric disorders.

Nebido (testosterone) solution for injection

SPC now states that improved insulin sensitivity may occur in patients treated with androgens who achieve normal testosterone plasma concentrations following replacement therapy. Therefore, the dosage of hypoglycaemic agents may need to be lowered.

Ongentys (opicapone) 50 mg hard capsules

SPC updated to include nausea as an adverse effect of common frequency

Medicines Safety Assurance Tool

November 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

Ovranette 150/30 micrograms Coated Tablets

SPC updated in line with PRAC recommendations, to note ALT elevations have been observed in people using ethinylestradiol-containing medications and products containing sofosbuvir/velpatasvir/voxilaprevir, and their concomitant use is contraindicated.

Rotarix (live attenuated rotavirus vaccine) oral suspension in squeezable tube

SPC updated with removal of reference to 'multi monodose'.

Sofradex (gramicidin/framycetin/dexamethasone) Ear / Eye Drops

SPC now includes adverse drug reaction of glaucoma (unknown frequency), notes use in pregnancy should be considered only if benefits outweigh risk & warns treatment should not be continued for >7days in absence of clinical improvement due to risk of occult extension of infections.

Synjardy 5 mg/850 mg (empagliflozin/metformin) film-coated tablets

SPC updated to reflect lowering of eGFR value for starting treatment in cohort that has both type 2 diabetes mellitus and established cardiovascular disease, so they can now be started on 10mg empagliflozin down to eGFR of 30 ml/min/1.73m².

Synphase (norethisterone, ethinylestradiol) 500 microgram / 35 microgram tablets and 1 milligram / 35 microgram Tablets

SPC now notes results from a large number of laboratory tests have been shown to be influenced by the use of oestrogen containing oral contraceptives including liver function.

Vaxneuvance (Pneumococcal polysaccharide conjugate vaccine [15-valent, adsorbed])

SPC updated to incorporate information on extension of license to include active immunisation for prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to less than 18 years of age.

Xarelto (rivaroxaban) 2.5 mg film-coated tablets

SPC updated to include eosinophilic pneumonia as a very rare adverse drug reaction.

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.

Copyright © Midlands and Lancashire Commissioning Support Unit

Medicines Safety Assurance Tool

November 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

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.