

Medicines Safety Assurance Tool

October 2021

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

[Emerade 300 microgram and 500 microgram adrenaline auto-injectors: re-supply to market – important safety information](#)

08 October 2021

Following satisfactory implementation of corrective actions, MHRA has agreed 300 and 500 microgram strengths of Emerade adrenaline autoinjectors can be re-supplied to market in Oct 2021. Emerade 150 microgram auto-injectors will not be returning to market at this time.

Proposed action

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



[Redacted area]

Action taken

[Redacted area]

Status	Action due date	Date completed
[Redacted]	[Redacted]	[Redacted]

Summary of Product Characteristics updates

[Amglidia \(glibenclamide\) 0.6 mg/mL and 6mg/ml oral suspension - Prescriber Guide](#)

This guide helps prescribers to select the most suitable presentation according to body weight and posology and provides guidance on how to avoid mixing presentations and dosing errors which could result in serious harm.

[Asacol \(mesalazine\) 400mg and 800mg MR Tablets](#)

Pleurisy has been added to SPC as an adverse effect.

Proposed action

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



[Redacted area]

Action taken

[Redacted area]

Status	Action due date	Date completed
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Midlands and Lancashire
Commissioning Support Unit

Brilique (ticagrelor) tablets– all strengths and formulations

SPC has been updated with information from phase III study (HESTIA 3) in 193 paediatric patients with sickle cell disease, which found no treatment benefit of ticagrelor on the rate of vaso-occlusive crises compared to placebo, therefore no data supports use in this population

Clexane (enoxaparin) pre-filled syringes

SPC updated to note licence extension for use as extended treatment of deep vein thrombosis and pulmonary embolism and prevention of its recurrence in patients with active cancer.

Comirnaty (Pfizer/BioNTech) concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)

The side effects decreased appetite, lethargy, hyperhidrosis; night sweats and asthenia have been added to SPC.

Coversyl Arginine (perindopril arginine) tablets

SPC notes that perindopril arginine must not be initiated earlier than 36 hours after the last dose of sacubitril/valsartan. It previously contra-indicated concomitant use owing to the increased risk of angioedema.

Daktacort 2%/1% w/w (miconazole/hydrocortisone) ointment and cream

SPC updated with severe hypersensitivity reactions, including anaphylaxis/angioedema reported with topical miconazole, close monitoring if patients on oral anticoagulants, adrenal suppression can occur even without occlusion and risk of topical steroid withdrawal syndrome.

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[Invokana \(canagliflozin\) 300 mg film-coated tablets](#)

SPC updated with addition of warnings regarding complicated urinary tract and kidney infections from post-marketing cases and advice to consider temporary interruption of canagliflozin treatment in patients with complicated urinary tract infections.

[Kenalog \(triamcinolone\) Intra-articular / Intramuscular Injection](#)

SPC now states that, as well as 'Steroid Treatment Cards', the patient should carry a 'Steroid Emergency Card' when multiple doses are given in a relatively short period of time.

[Lamictal \(lamotrigine\) Dispersible](#)

SPC now notes that partial dosing should not be performed when using the dispersible/chewable tablets (applicable to all dispersible/chewable tablet strengths).

[Saxenda \(liraglutide\) pre-filled pen](#)

SPC has been updated to reflect the licence extension for use (as an adjunct to a healthy nutrition and increased physical activity) for weight management in adolescents (≥ 12 years) with obesity BMI corresponding to ≥ 30 kg/m² for adults) and body weight above 60kg.

[Teragezza \(cyproterone acetate; ethinylestradiol\) Film-coated Tablets](#)

SPC updated with caution that exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema (frequency 'unknown').

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Tildiem (diltiazem) Prolonged-Release Capsules

SPC now notes that concurrent use with lomitapide and asunaprevir is contraindicated as diltiazem may increase plasma concentrations of these agents owing to CYP3A4 inhibition.

Varilrix (varicella-zoster virus vaccine) 10 3.3 PFU/0.5ml, powder and solvent for solution for injection

SPC now includes excipient warning regarding phenylalanine content which may be harmful for individuals with phenylketonuria, updated refrigeration detail to include transport and statement regarding storage in the original package in order to protect from light.

Zydol (tramadol) XL 400 mg prolonged-release Tablets

Syncope has been added to SPC as a rare adverse 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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