

Medicines Safety Assurance Tool

May 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

Management of chronic asthma in children aged 16 years and under - Report

05 May 2021

Report was produced following a case of a near fatal attack of asthma in a 5 year old. It makes seven recommendations that provide system solutions to the management of asthma. They focus broadly on developing resources to encourage behaviour change and information sharing.

Proposed action

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



Action taken

Status	Action due date	Date completed

Levothyroxine: new prescribing advice for patients who experience symptoms on switching between different levothyroxine products

19 May 2021

If a patient reports persistent symptoms when switching between different levothyroxine tablet formulations, consider consistently prescribing a specific product known to be well tolerated by the patient. If symptoms or poor control of thyroid function persist (despite adhering to a specific product), consider prescribing levothyroxine in an oral solution formulation.

Proposed action

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



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Summary of Product Characteristics updates

[AVAXIM \(hepatitis A vaccine\) suspension for injection in a pre-filled syringe](#)

SPC updated to advise that it contains 10mcg phenylalanine per 0.5ml dose, equivalent to 0.17mcg/kg for a 60kg person. Phenylalanine may be harmful for those with phenylketonuria, a rare genetic disorder in which phenylalanine builds up as the body cannot remove it properly.

[Eliquis \(apixaban\) 2.5 mg film-coated tablets](#)

Section 4.4 relating to patients with active cancer revised with statement that this group can be at high risk of both VTE and bleeding events, and when apixaban is considered for DVT or PE treatment, a careful assessment of the benefits against the risks should be made.

[Epistatus \(midazolam\) 10 mg Oromucosal Solution](#)

Angioedema has been added as an adverse effect of unknown frequency.

[Fentanyl \(Effentora\) Buccal Tablets](#)

SPC now notes opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. In patients who present with CSA, consider decreasing the total opioid dosage.

[Lyumjev \(insulin lispro\) – all products](#)

Paediatric data, showing pharmacokinetic differences between Lyumjev and Humalog similar to that seen in adults have been added to SPC but no recommendation on posology can be made. Also SPC now states no differences in safety/effectiveness with use in elderly & younger patients. Data also added from PRONTO-T1D and PRONTO-T2D (multiple-dose injection administration) studies noting injection site reactions occurred in 2.7 % of patients treated with Lyumjev, and from PRONTO-Pump-2 study, noting infusion site reactions reported in 38 % of patients on Lyumjev.

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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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Minims Phenylephrine Hydrochloride 10%w/v Eye drops, solution

Now contraindicated for children below 12 years old due to since serious systemic adverse reactions reported with ophthalmic products containing phenylephrine and not recommended for children aged 12-18 years old due to lack of data in this age group.

Neurontin (gabapentin) Tablets

SPC warns of risk of fatal respiratory depression with concomitant administration with opioid-containing drugs and other CNS depressants. Patients who require concomitant treatment should be carefully observed for signs, such as somnolence, sedation, and respiratory depression.

PecFent (fentanyl) 100 and 400 micrograms/spray nasal spray, solution

SPC now includes section on opioid use disorder and warns opioids can cause sleep-related breathing disorders including central sleep apnoea. Cheynes Stokes respiration has been added as symptom that may occur in context of overdose.

Phenergan (promethazine) Elixir

Restless legs syndrome has been added as an adverse effect

Picolax (sodium picosulfate; magnesium oxide; citric acid) powder for oral solution

SPC warns that the additional clear liquid to be taken with this product should not be only water. Drinking only water may lead to electrolyte imbalance, which in severe cases, may lead to complications such as seizures and coma.

Vokanamet 50 mg/850 mg and 50 mg/1000 mg (canagliflozin /metformin) coated tablets

SPC now warns that post-marketing cases of complicated UTIs including pyelonephritis and urosepsis have been reported in patients treated with canagliflozin, frequently leading to treatment interruption. Temporary interruption should be considered if this occurs.