Medicines Safety Assurance Tool

July 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

NHS
Midlands and Lancashire
Commissioning Support Unit

Chloramphenicol eye drops containing borax or boric acid buffers: use in children younger than 2 years

08 July 2021

Following review of toxicological data & calculation of daily exposure to boron from typical dosing regimen, MHRA has concluded risk vs benefits of chloramphenicol eye drops containing borax/boric acid remains positive for children aged 0 to 2 years and can be safely administered.

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status	Action due date	Date completed

Herbal and homeopathic medicines: reminder to be vigilant for suspected adverse reactions and to report them to the Yellow Card scheme

08 July 2021

If an adverse drug reaction is suspected, ask patients if they are taking any herbal or homeopathic medicines and report any suspicions to the Yellow Card scheme. Remind patients to check that a herbal or homeopathic medicine is licensed and to follow the advice included in the patient information.

Proposed action

☑ Newsletter ☐ Optimise Rx/ScriptSwitch

☐ Practice audit/search ☐ Other (please specify)

Action taken

Status	Action due date	Date completed

Inappropriate anticoagulation of patients with a mechanical heart valve

14 July 2021

This alert asks GPs and other NHS providers of anticoagulation services to identify patients with a record of a mechanical heart valve and receiving a DOAC, and to urgently review these patients to ensure they are on the most appropriate anticoagulation therapy and monitoring.

Proposed action

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

Action taken

Status | Action due date | Date completed

Understanding safety risks with betamethasone soluble tablets used as mouthwash

15 July 2021

National Reporting & Learning System has received number of reports related to betamethasone soluble tablets prescribed as mouthwash but mistakenly taken orally. One report described hospital admission for adrenal crisis. Providing clear patient directions can help prevent harm.

Proposed action

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

Action taken

Status | Action due date | Date completed

Proposed action

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

Action taken

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Summary of Product Characteristics updates

Aprovel (irbesartan) and CoAprovel (hydrochlorthiazide with irbesartan) tablets

SPC now notes that hypoglycaemia can occur with these products, particularly in diabetic patients. In patients treated with insulin or antidiabetics an appropriate blood glucose monitoring should be considered; a dose adjustment of insulin or antidiabetics may be required.

CoAprovel (hydrochlorothiazide and irbesartan) 150 mg/12.5 mg film-coated tablets

SPC updated to include interaction with repaglinide due to potential inhibition of OATP1B1 by irbesartan which may require dose adjustment of repaglinide. Adverse effects of hypoglycaemia and anaemia added with unknown frequencies.

Clorogen (chloramphenicol) Eye Drops 0.5% w/v

The contraindication to use in children less than 2 years of age due to concerns about boron and impairment of fertility in the future has been removed following MHRA review of available toxicological data.

Covonia Original Bronchial Balsam Syrup (dextromethorphan and menthol)

SPC updated to note that prolonged use may lead to drug dependence (addiction), even at therapeutic doses. Risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression).

Dyzantil (sodium valproate/valproic acid) prolonged-release tablets

SPC updated to note co-administration of sodium valproate with metamizole (inducer of metabolising enzymes; not available in UK) may cause reduction in plasma concentrations of sodium valproate with potential decrease in efficacy; caution therefore advised when co-administered.

Efracea (doxycycline) 40mg Modified Release Hard Capsules

Data from the ANSWER study, evaluating doxycycline modified-release capsules (versus placebo) added to ivermectin for the treatment of adults with severe rosacea have been added to the SPC.

Hibiscrub (chlorhexidine Gluconate 4% w/v)

SPC updated to highlight that Hibiscub now contains soya oil therefore it is contraindicated in patients allergic to peanut or soya. Soya oil content in Hibiscrub is 0.000012% w/w.

Levemir (insulin detemir) InnoLet 100 units/ml solution for injection- all presentations

SPC now notes that post-marketing data in pregnant women using Levemir, with more than 4,500 pregnancy outcomes do not indicate any increased risk of malformative or feto/neonatal toxicity.

Meningococcal B: vaccine information for healthcare professionals (revised)

This document contains information for healthcare professionals regarding the immunisation against meningococcal B disease for infants aged from 2 months. The section on missed doses of Bexsero has been updated.

Methadone Hydrochloride preparations (Rosemont)

SPC updated to note co-administration with metamizole (inducer of metabolising enzymes) may cause a reduction in plasma concentrations of methadone with potential decrease in clinical efficacy. Therefore, caution is advised when administered concurrently.

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

SPC updated to note there have been post-marketing reports of serotonin syndrome when naltrexone/bupropion was co-administered with a serotonergic agent, such as SSRIs or SNRIs, and that post-marketing cases of hypertensive crisis have been reported during the initial titration.

Nicorette (nicotine) QuickMist SmartTrack 1mg/spray mouthspray

SPC updated to note the potential risks and benefits of nicotine should be carefully evaluated before use in those with a history of epilepsy as cases of convulsions have been reported in association with nicotine. Seizures (frequency unknown) has been added as an adverse event.

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

ALT elevations were observed in women on glecaprevir/pibrentasvir, who were using ethinylestradiol-containing medications such as combined oral contraceptives, thus use of Synpase with products containing glecaprevir/pibrentasvir is now contraindicated.

Xarelto (rivaroxaban) patient alert card

This alert card noting the patient's anticoagulation treatment with rivaroxaban should be presented to any physician or dentist, prior to treatment. It also contains information for the patient on how to take the medicine, and when to seek advice.

Zirtek Allergy Relief (cetirizine) 10 mg film-coated Tablets

SPC updated to note use in patients with end-stage renal disease with a GFR <15mL/min (previously <10ml/min) is contra-indicated, and the GFR ranges requiring dose adjustments have been altered slightly. Myalgia has been added as an adverse event (unknown frequency).