New MHRA drug safety advice: August to October 2013

Document as included in MAW

The MHRA and CHM publish the monthly newsletter Drug Safety Update highlighting important information and advice to support the safer use of medicines. To subscribe to Drug Safety Updates from the MHRA, please visit this link to register.

The MHRA has provided the following synopsis of the key drug safety issues from the August, September and October 2013 Drug Safety Updates:

Intravenous iron and serious hypersensitivity reactions: new strengthened recommendations to manage and minimise risk¹
A Europe-wide review of intravenous iron products for iron deficiency and anaemia has recommended that strengthened measures are taken to manage and minimise the risk of hypersensitivity reactions, which may be life-threatening or fatal as outlined in the article.

Caffeine for apnoea of prematurity: all products to be named and prescribed as caffeine citrate²
In order to minimise potential risk to premature newborns when prescribing or dispensing, the name of caffeine products supplied by Viridian Pharma Limited is being changed to caffeine citrate. This change brings the Viridian products in line with the naming of other products available on the UK market, which are already named in the salt form as caffeine citrate. All product doses should be prescribed as caffeine citrate, taking into account the different strengths of the marketed products.

Nitrofurantoin: reminder on precautions for use, especially renal impairment in elderly patients³
Use of nitrofurantoin for urinary tract infections is contraindicated in patients with less than 60 mL/min creatinine clearance. Healthcare professionals should be aware of patients’ current renal function when prescribing, especially in elderly patients.

Product information should also be consulted in relation to established risks of nitrofurantoin, which include pulmonary toxicity, hepatic toxicity, peripheral neuropathy, and contraindications in G6PD deficiency and acute porphyria.

Oral ketoconazole: do not prescribe or use for fungal infections—risk of liver injury outweighs benefits⁴
Doctors should no longer prescribe oral ketoconazole for fungal infections, and should review patients’ treatment options because of a risk of liver injury. The European Medicines Agency’s Committee on Medicinal Products for Human Use (CHMP) concluded that although liver injury such as hepatitis is a known side effect of antifungal medicines, the incidence and the seriousness are higher with oral ketoconazole than with other antifungals.

Metoclopramide: risk of neurological adverse effects—restricted dose and duration of use

The CHMP has reviewed the benefits and risks of the antiemetic metoclopramide. The review has recommended changes that include a restriction to the dose and duration of use to help minimise the risk of potentially serious neurological adverse effects.

Filgrastim and pegfilgrastim: risk of potentially life-threatening capillary leak syndrome

Capillary leak syndrome (CLS) has been reported in recipients of filgrastim, including patients undergoing chemotherapy and a healthy donor undergoing peripheral blood progenitor-cell mobilisation; it has also been reported in recipients of pegfilgrastim undergoing chemotherapy. Episodes varied in severity and frequency. CLS is characterised by: hypotension and oedema; hypoalbuminaemia; and haemoconcentration, and may be fatal unless promptly diagnosed and managed.

Prescribers should monitor patients and healthy donors for signs and symptoms of CLS, and should give standard symptomatic treatment immediately if symptoms occur. Patients should be advised to seek medical attention immediately if they experience symptoms of CLS.

Panitumumab: importance of establishing wildtype RAS (KRAS and NRAS) status before treating metastatic colorectal cancer

In the treatment of metastatic colorectal cancer, evidence of wildtype RAS status (at exons 2, 3, and 4 of KRAS and NRAS) is required before initiating treatment with panitumumab alone or in combination with chemotherapy. Inferior progression-free survival and overall survival have been shown in patients with RAS mutations beyond KRAS exon 2 who received panitumumab combined with FOLFOX (oxaliplatin-containing) chemotherapy, compared with FOLFOX alone.

New oral anticoagulants apixaban (Eliquis▼), dabigatran (Pradaxa) and rivaroxaban (Xarelto▼): risk of serious haemorrhage—clarified contraindications applied to all 3 medicines

The MHRA previously advised that the contraindications for dabigatran had been clarified to include a range of clinical conditions where the patient is at significant risk of major bleeding, as well as in combination with other anticoagulant agents. Because similar risks are associated with the other new oral anticoagulants (apixaban and rivaroxaban), these contraindications have been applied across all three new oral anticoagulants for all indications and doses.

The process used to produce Drug Safety Update is NICE accredited.

References

4. Drug Safety Update August 2013. Volume 7, issue 1: S1
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