

Drug Safety Update



Latest advice for medicines users

The monthly newsletter from the Medicines and Healthcare products Regulatory Agency and its independent advisor the Commission on Human Medicines

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The Medicines and Healthcare products Regulatory Agency is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

The Commission on Human Medicines gives independent advice to ministers about the safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.



The MHRA is accredited by NICE to provide Drug Safety Update. Further information can be found on the NICE Evidence Search portal: www.evidence.nhs.uk/

This month, we provide updated advice for the use of hyoscine butylbromide (Buscopan) for injection. Adverse effects associated with hyoscine butylbromide for injection can be more serious in patients with underlying cardiac disease, such as those with heart failure, coronary heart disease, cardiac arrhythmia, or hypertension. Healthcare professionals should monitor these patients, and ensure that resuscitation equipment, and personnel who are trained how to use this equipment, are readily available. Further information is on page 2.

We also feature news of the integration of Yellow Card reporting into Vision. This is an important step towards making it as easy and convenient as possible for busy healthcare professionals to report suspected adverse reactions to medicines (see page 3).

drugsafetyupdate@mhra.gsi.gov.uk

Hyoscine butylbromide (Buscopan) injection: risk of serious adverse effects in patients with underlying cardiac disease

Prescribing information has been updated to help to minimise the risk of serious adverse reactions in patients with cardiac disease.

Advice for healthcare professionals:

- hyoscine butylbromide injection can cause serious adverse effects including tachycardia, hypotension, and anaphylaxis
- these adverse effects can result in a fatal outcome in patients with underlying cardiac disease, such as those with heart failure, coronary heart disease, cardiac arrhythmia, or hypertension
- hyoscine butylbromide injection should be used with caution in patients with cardiac disease
- monitor these patients, and ensure that resuscitation equipment, and personnel who are trained how to use this equipment, are readily available
- hyoscine butylbromide injection remains contraindicated in patients with tachycardia

Background

Hyoscine butylbromide (Buscopan), given intravenously or intramuscularly, is indicated in acute muscular spasm, as in renal or biliary colic; in radiology for differential diagnosis of obstruction and to reduce spasm and pain in pyelography; and in other diagnostic procedures where spasm may be a problem (eg, gastroduodenal endoscopy).

Risk of adverse reactions

We have received 9 reports of patients who died after receiving hyoscine butylbromide injection (including [a report](#) from a coroner). In most of these cases, the fatal adverse reaction was reported as acute myocardial infarction or cardiac arrest.

Hyoscine butylbromide injection can cause adverse effects including tachycardia, hypotension, and anaphylaxis. These effects can be more serious in patients with underlying cardiac disease (eg, heart failure, coronary heart disease, cardiac arrhythmia, or hypertension). Several reports have noted that anaphylaxis is more likely to be fatal in patients with underlying coronary heart disease compared with those without.^{1,2}

Reporting of suspected adverse reactions

Suspected adverse reactions should be reported to us on a [Yellow Card](#).

Article citation: Drug Safety Update volume 10 issue 7, February 2017: 1.

1. Mueller UR. [Cardiovascular disease and anaphylaxis](#). Curr Opin Allergy Clin Immunol 2007; 7: 337–41.

2. Triggiani M, et al. [Allergy and the cardiovascular system](#). Clin Exp Immunol 2008; 153: 7–11.

Yellow Card reporting added to second clinical software system

Healthcare professionals who use Vision can now report suspected adverse reactions to MHRA directly through their clinical software.

Electronic Yellow Card reporting of suspected adverse drug reactions is being integrated into Vision, the general practice system software. This functionality is a huge step forward in accessibility of the [Yellow Card Scheme](#) to healthcare professionals.

Integration of Yellow Card reporting into clinical systems makes it easy to complete and send a Yellow Card because much of the information needed can be automatically populated from patient records. At the same time, electronic reporting provides a secure, fast, and convenient method for submitting information about suspected adverse drug reactions.

Vision is the second clinical system supplier to implement this functionality. After the 2010 introduction of electronic Yellow Card reporting into SystmOne clinical software by The Phoenix Partnership, we have seen a large increase in the number of reports from general practice. In 2016, 21% (5708) of directly reported Yellow Cards were received from the SystmOne system users.

Increased numbers of Yellow Cards makes more data available to us to identify possible drug safety issues promptly, and so helps to protect public health.

As part of the requirements under the NHS [GP Systems of Choice Programme](#) (GPSoC), all suppliers of primary care systems must integrate electronic Yellow Card facilities into their clinical software. We are establishing timelines with other suppliers as to when this reporting functionality will be added into their systems.

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Letters sent to healthcare professionals in January 2017

In January 2017, letters were sent regarding:

- Insuman (human insulin): end of supply shortage ([letter to healthcare professionals](#) and [letter to patient organisations](#))
- Mirena (levonorgestrel intrauterine delivery system): [batch insertion tube defect](#)
- Ulipristal acetate (ellaOne): [pregnancy registry](#)
- ERWINASE: notice of special handling instructions—[vials of ERWINASE from batch 180G should be used with a 5-micron filter needle](#)

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