

衛生署藥物辦公室
藥物註冊及進出口管制部

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本署檔號 OUR REF.: DH DO PRIE/7-30/15

21 February 2017

(來函請敘明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

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

Your attention is drawn to the Medicines and Healthcare products Regulatory Agency's (MHRA) announcement regarding an update on prescribing information in the United Kingdom (UK) to help to minimise the risk of serious adverse reactions in patients with cardiac disease.

Hyoscine butylbromide (Buscopan), given intravenously or intramuscularly, is indicated in UK 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).

The MHRA has 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). MHRA noted, based on several reports, anaphylaxis is more likely to be fatal in patients with underlying coronary heart disease compared with those without.

The MHRA advised healthcare professionals of the following:

- 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.

Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/hyoscine-butylbromide-buscopan-injection-risk-of-serious-adverse-effects-in-patients-with-underlying-cardiac-disease>

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In Hong Kong, there are 7 registered pharmaceutical products of hyoscine injection. So far, the Department of Health has not received any adverse drug reaction report on cardiac side effects after receiving hyoscine injection. In view of the above MHRA announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Joseph LEE)

for Assistant Director (Drug)