Dear Healthcare Professional,

HYOSCINE BUTYLBROMIDE INJECTION: RISK OF SERIOUS ADVERSE EFFECTS IN PATIENTS WITH UNDERLYING CARDIAC DISEASE

The Food and Drugs Authority (FDA) wishes to bring to your attention a follow up to the publication in the 2017 edition of the FDA’s DrugLens, safety information from the UK Medicines and Healthcare products Regulatory Agency (MHRA) relating to reports of acute myocardial infarction or cardiac arrest with fatal outcomes associated with the use of hyoscine butylbromide injection.

Hyoscine butylbromide 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).

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). Studies have suggested that anaphylaxis is more likely to be fatal in patients with underlying coronary heart disease compared with those without.

Healthcare professionals are therefore advised to take note of the underlisted:

1. Hyoscine butylbromide injection can cause serious adverse effects including tachycardia, hypotension, and anaphylaxis.

2. 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.

3. Hyoscine butylbromide injection should be used with caution in patients with cardiac disease.

References:
4. Monitor these patients, and ensure that resuscitation equipment, and personnel who are trained how to use this equipment, are readily available.

5. Hyoscine butylbromide injection remains contraindicated in patients with tachycardia.

The FDA has requested all marketing authorization holders to update prescribing information to reflect this new safety information.

Healthcare professionals are advised to report adverse drug reactions to hyoscine butylbromide injection and all other medicines to the FDA by completing the Adverse Reaction Reporting Form or online using the link http://adr.fdaghana.gov.gh/ or call 0244310297 or send an email to drug.safety@fdaghana.gov.gh.

Yours faithfully,

Signed

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