CENTRAL PROCUREMENT & SUPPLIES UNIT
MINISTRY FOR HEALTH

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Internal Memo: MFH^Health^29^2017

Ref: 04/2017/FS 5 December 2017

Direct Healthcare Professional Communication

Risk of increased levels of histamine with Gentamicin Injectable preparations

Dear Healthcare Professional,

The Central Procurement and Supplies Unit (CPSU) within the Ministry for Health, in agreement with the Malta Medicines Authority would like to inform you of the following safety concern.

Summary

The CPSU has issued a letter for caution in use of Gentamicin Injections containing batches of Gentamicin Sulphate Active Pharmaceutical Ingredient (API) which may contain higher than expected levels of histamine.

This is the result of a product quality defect, which is a residual from the manufacturing process associated with batches of API produced between the second half of 2014 and June 2017 that are potentially affected. A recall is not considered appropriate at this stage.

Healthcare professionals are advised to be cautious when using the product listed hereunder, in particular when using Gentamicin concomitantly with drugs known to cause histamine release (for example opioids and muscle relaxants).

Product Description	**UK Licence Holder**	**UK Licence Number**	**Registration Number in Malta**
Gentamicin 40mg/ml Solution for Injection	Amdipharm UK Limited	PL20072/0056	AA565/10701

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Background on Safety Concern

Gentamicin is an aminoglycoside antibiotic with broad-spectrum bactericidal activity. It is usually active against most strains of the following organisms: Escherichia coli, Klebsiella spp., Proteus spp. (indole positive and indole negative), Pseudomonas aeruginosa, Staphylococci, Enterobacter spp., Citrobacter spp. and Providencia spp. Gentamicin Intrathecal Injection is indicated as a supplement to systemic therapy in bacterial meningitis, ventriculitis and other bacterial infections of the central nervous system, whilst Gentamicin 40 mg/ml injection is indicated in adolescents, children and adults for the treatment of systemic infections due to susceptible bacteria such as, bacteraemia, septicaemia, urinary-tract infections and severe chest infections in line with official local guidance on the appropriate use of antibacterial agents.

Patients treated with the above product should be monitored closely for potential adverse reactions associated with increased levels of histamine, which may cause anaphylactoid (for example flushing, itching, urticaria and shortness of breath) or hypotensive reactions and increased heart rate. In particular, heart rate and blood pressure should be monitored throughout administration. Paediatric patients and patients with severe renal impairment may be more susceptible to the effects of exogenous histamine, therefore these patients should be monitored more closely.

Recipients of this Drug Alert should bring it to the attention of relevant hospital pharmacists, hospital clinicians, nurses and operating theatre staff and the relevant Healthcare Professionals where the product is being used in a domiciliary setting.

Call for Reporting

Healthcare professionals are reminded to report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system. Any suspected adverse reactions and medication errors can be reported via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from the portal of the Malta Medicines Authority www.medicinesauthority.gov.mt/adrportal and addressed to the Post-licensing Department, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta or sent by email to postlicensing.medicinesauthority@gov.mt

CPSU Contact Point

Further questions or requests for additional information may also be addressed to the Central Procurement and Supplies Unit, San Ġwann Industrial Estate, Malta.

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