Epidural Corticosteroid Injection - Risk of Rare But Serious Neurologic Problems

Your attention is drawn to the US Food and Drug Administration’s (FDA) announcement on warning healthcare professionals that injection of corticosteroids, including methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone, into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating pain in the arms and legs. FDA required the addition of a Warning to the drug labels of injectable corticosteroids to describe these risks.

Injectable corticosteroids are commonly used to reduce swelling or inflammation. Injecting corticosteroids into the epidural space of the spine has been a widespread practice for many decades; however, the effectiveness and safety of epidural administration of corticosteroids had not been established, and FDA has not approved corticosteroids for this use.

Healthcare professionals are advised to discuss with patients the benefits and risks of epidural corticosteroid injections and other possible treatments and counsel patients to seek emergency medical attention immediately if they experience symptoms after receiving an epidural corticosteroid injection.

Please refer to FDA’s website for details:

In Hong Kong, there are 25 registered injectable products containing corticosteroids such as methylprednisolone, hydrocortisone, triamcinolone, betamethasone and dexamethasone. All the products are prescription only medicines. So far, the Department of Health has not received any adverse drug reaction report in relation to epidural injection of the drugs. In view of FDA’s announcement, the matter will be discussed in the meeting of 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 encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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 sincerely,

[Signature]

(Mr. Grant NG)
for Assistant Director (Drug)

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continue to be an internationally renowned public health authority