U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Epidural Corticosteroid Injection: Drug Safety Communication - Risk of Rare But Serious Neurologic Problems

Including methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone

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AUDIENCE: Pain Management, Anesthesiology

ISSUE: FDA is warning that injection of corticosteroids 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. The effectiveness and safety of epidural administration of corticosteroids have not been established, and FDA has not approved corticosteroids for this use.

FDA is requiring the addition of a Warning to the drug labels of injectable corticosteroids to describe these risks.

BACKGROUND: To raise awareness of the risks of epidural corticosteroid injections in the medical community, FDA's Safe Use Initiative convened a panel of experts, including pain management experts to help define the techniques for such injections which would reduce preventable harm. The expert panel's recommendations will be released when they are finalized. FDA will convene an Advisory Committee meeting of external experts in late 2014 to discuss the benefits and risks of epidural corticosteroid injections and to determine if further FDA actions are needed.

RECOMMENDATION: Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments. See the Drug Safety Communication for a Data Summary and additional information for both patients and healthcare professionals.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: **www.fda.gov/MedWatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
- **Download form (/Safety/MedWatch/HowToReport/DownloadForms/default.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[04/23/2014 - **Drug Safety Communication (/Drugs/DrugSafety/ucm394280.htm)** - FDA]