

Drug Safety Communications

FDA Drug Safety Communication: FDA requires label changes to warn of rare but serious neurologic problems after epidural corticosteroid injections for pain

Safety Announcement

[4-23-2014] The U.S. Food and Drug Administration (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. We are requiring the addition of a *Warning* to the drug labels of injectable corticosteroids to describe these risks. 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.

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 the drugs for this use have not been established, and FDA has not approved corticosteroids for such use. We started investigating this safety issue when we became aware of medical professionals' concerns about epidural corticosteroid injections and the risk of serious neurologic adverse events.¹ This concern prompted us to review cases in the FDA Adverse Event Reporting System (FAERS) database and in the medical literature (see Data Summary).²⁻¹⁶

To raise awareness of the risks of epidural corticosteroid injections in the medical community, <u>FDA's Safe Use Initiative</u> 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.

As part of FDA's ongoing effort to investigate this issue, we plan to 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.

Injectable corticosteroids include methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone. This safety issue is unrelated to the contamination of compounded corticosteroid injection products reported in 2012.

Facts about corticosteroids

- A class of drugs commonly used to reduce swelling or inflammation
- Injectable corticosteroids include methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone

Corticosteroids are not approved by FDA for injection into the epidural space of the spine.

Additional Information for Patients

- Rare but serious problems have occurred after injection of corticosteroids into the epidural space of the spine to treat neck and back pain, and radiating pain in the arms and legs. These serious problems include loss of vision, stroke, paralysis, and death.
- The effectiveness and safety of injection of corticosteroids into the epidural space of the spine have not been established, and FDA has not approved corticosteroids for this use.
- Discuss the benefits and risks of epidural corticosteroid injections with your health care professional, along with the benefits and risks associated with other possible treatments.
- Seek emergency medical attention immediately if you experience any unusual symptoms after
 receiving an epidural corticosteroid injection, such as loss of vision or vision changes; tingling in your
 arms or legs; sudden weakness or numbness of your face, arm, or leg on one or both sides of the
 body; dizziness; severe headache; or seizures.
- Report any side effects from epidural corticosteroid injections to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Additional Information for Health Care Professionals

- Rare but serious neurologic adverse events have been reported with epidural corticosteroid
 injections, including spinal cord infarction, paraplegia, quadriplegia, cortical blindness, stroke, and
 death.
- These serious neurologic events have been reported with and without the use of fluoroscopy.
- The effectiveness and safety of epidural administration of corticosteroids have not been established, and FDA has not approved corticosteroids for this use.
- Discuss with patients the benefits and risks of epidural corticosteroid injections and other possible treatments.
- Counsel patients to seek emergency medical attention immediately if they experience symptoms
 after receiving an epidural corticosteroid injection, such as loss of vision or vision changes; tingling in
 their arms or legs; sudden weakness or numbness in their face, arm, or leg on one or both sides of
 the body; dizziness; severe headache; or seizures.
- Report adverse effects following epidural corticosteroid injections to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Data Summary

FDA reviewed a sampling of cases from the FDA Adverse Event Reporting System (FAERS) database, as well as cases in the medical literature of serious neurologic adverse events associated with epidural corticosteroid injections. ²⁻¹⁶ Serious adverse events included death, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, stroke, seizures, nerve injury, and brain edema. Many cases were temporally associated with the corticosteroid injections, with adverse events occurring within minutes to 48 hours after the corticosteroid injections. In some cases, diagnoses of neurologic adverse events

were confirmed through magnetic resonance imaging or computed tomography scan. Many patients did not recover from these reported adverse events.

References

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