



FDA Drug Safety Communication

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

The 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. 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.

Rare but serious problems and neurologic events 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, paralysis, 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 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

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.