

# Spinal Corticosteroids Run Risk of Severe Neuro Effects

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Epidural injections of corticosteroids to relieve pain — a widespread, off-label use — run the rare risk for blindness, stroke, paralysis, and death, the US Food and Drug Administration (FDA) announced today.

The FDA is requiring manufacturers of corticosteroids to revise drug labels to include this warning.

In today's announcement, directed at anesthesiologists and pain management physicians, the agency said it has not established the effectiveness and safety of epidural administration of corticosteroids such as hydrocortisone and methylprednisolone. As a consequence, "the FDA has not approved corticosteroids for such use."

The agency said it began to investigate the neurological risks for epidural injections of corticosteroids at the behest of worried clinicians. This led to a review of the FDA Adverse Event Reporting System and the medical literature. The FDA said it found that in many cases of epidural injections gone awry, the adverse effects were temporary, occurring within minutes to 48 hours after treatment. However, many other patients did not recover from the reported adverse events, which also included brain edema and seizures.

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The FDA is advising clinicians to discuss with patients the benefits and risks for epidural corticosteroid injections and alternative therapies. They also should counsel patients to seek emergency medical care if they experience vision loss; tingling in their extremities; sudden weakness or numbness in their face, arm, or leg on one or both sides of their body; seizures; dizziness; or severe headaches after an injection.

More information on today's announcement is available on the FDA [Web site](#).

To report problems with epidural injections of corticosteroids, contact MedWatch, the FDA's safety information and adverse

event reporting program, by telephone at 1-800-FDA-1088 begin\_of\_the\_skype\_highlighting 1-800-FDA-1088 FREE end\_of\_the\_skype\_highlighting; by fax at 1-800-FDA-0178; online at

<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>; with postage-paid FDA form 3500, available at <http://www.fda.gov/MedWatch/getforms.htm>; or by mail to MedWatch, 5600 Fishers Lane, Rockville, Maryland 20852-9787.

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