Generic Name:
Cesium chloride
Trade Name:
No trade name
Company:
Multiple companies
Notes:

FDA is moving cesium chloride (CsCl) to the category of bulk drug substances (active pharmaceutical ingredients) that present significant safety risks in compounding. CsCl is a mineral salt that is sometimes taken either orally or by injection by cancer patients who seek alternative treatments; however, no CsCl products have been approved by FDA to treat cancer or other diseases. Use of cesium poses significant safety risks (e.g., heart toxicity) and is potentially associated with death. These events can occur with oral administration and/or injection.

FDA intends to take action, such as issuing a warning letter or pursuing a seizure of product or injunction, if it encounters compounding using substances placed in this category.

FDA reviewed all adverse events related to CsCl and other cesium salts that were reported to FDA or that were published in medical journals through June 30, 2018. FDA identified 23 reports describing serious adverse events associated with cesium, including heart problems.

Five reports submitted to FDA and 18 published in the medical literature described patients who experienced adverse events from cesium. Seventeen of those reports were associated with CsCl, compared to 6 with other cesium salts like cesium carbonate. Most patients took cesium to try to treat cancer. The doses described in these cases ranged from 500 mg taken every day to 100 g taken over 11 days. Most reports did not identify where the cesium was obtained. In at least eight of these cases, health professionals measured cesium concentrations in the bodies of cesium users and found measured quantities that were several hundred to thousand-fold higher than normal.

Reported adverse events included QT prolongation, low potassium, seizures, potentially lethal arrhythmias, fainting, cardiac arrest, and death. QT prolongation was the most frequently reported adverse event. QT prolongation in the presence of low potassium usually improves quickly when potassium is administered, but 9 out of 11 of these patients receiving the potassium treatment either did not respond as well as expected or did not respond at all. Of the remaining two patients, one improved as expected, and one had an unknown response. Three patients were treated with a cesium-binding agent called Prussian Blue and had an improvement in the QT within a few days.

For others, it took several weeks after the cesium was stopped for their QT prolongation to improve. This is probably because when cesium is taken on an ongoing basis, it leaves the body very gradually and may take from 6 months to 2 years to be eliminated.

Six deaths were reported with use of cesium. FDA considers two of these deaths to be possibly associated with cesium chloride. The reports for these two deaths described cardiac arrest or arrhythmia occurring during, or within 24 hours of injection, of cesium. Three reports did not describe the cause of death, and one person may have died from advanced cancer and bloodstream infection.

Medication Monitor Categories:
Alerts and Recalls

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