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FDA Drug Safety Communication: FDA alerts healthcare professionals to stop performing heart scans with CardioGen-82 due to potential for increased radiation exposure in patients

This update is in follow-up to the Drug Safety Communication: Increased radiation exposure due to undetected strontium breakthrough when using CardioGen-82 for cardiac positron emission tomography (PET) scans¹ issued on 7/15/2011.

[7-26-2011] The U.S. Food and Drug Administration (FDA) is alerting healthcare professionals to stop using CardioGen-82 for cardiac positron emission tomography (PET) scans. The manufacturer, Bracco Diagnostics, Inc. has decided to voluntarily recall CardioGen-82.

CardioGen-82 consists of a generator that is used at clinical sites to produce rubidium (Rb)-82 chloride injection. A CardioGen-82 PET scan is one of a variety of nuclear medicine scans that use radioactive drugs to evaluate the heart.

On July 15, 2011², FDA alerted the public, in particular, the medical imaging community, about the potential for inadvertent, increased radiation exposure in patients who underwent or will be undergoing cardiac PET scans with rubidium (Rb)-82 chloride injection from CardioGen-82. As previously described, FDA has received report of two patients who received more radiation than expected from CardioGen-82. FDA believes that the risk of harm from this exposure is minimal, though exposure to any excessive radiation is undesirable. The estimated amount of excess radiation the two patients received is similar to that other patients may receive with cumulative exposure to certain other types of heart scans.

Based on further investigation, FDA has determined that the current CardioGen-82 manufacturing procedures are not sufficient to ensure reliable performance of the generator used to produce the Rb-82 chloride injection. Reliable generator performance is essential to help prevent strontium breakthrough from CardioGen-82 and to prevent patients from being exposed to excess radiation. FDA is also currently investigating the sufficiency of the testing procedures used to detect strontium breakthrough at the clinical sites that use CardioGen-82.

FDA recommends that healthcare professionals use alternatives to the CardioGen-82 generator when planning nuclear medicine cardiac scans. Patients who have any questions or concerns should talk to their healthcare professional.

FDA continues to work with the Nuclear Regulatory Commission and the CardioGen-82 manufacturer to determine the root cause for the increased radiation exposure detected in the two patients. The extent to which any additional patients may have received inadvertent radiation exposure is also under investigation. FDA plans to notify the public with updates.

Related Information

- [FDA Drug Safety Communication: Increased radiation exposure due to undetected strontium breakthrough when using CardioGen-82 for cardiac positron emission tomography \(PET\) scans³](#)
7/15/2011

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