



October 2015

**GE Healthcare
Life Sciences -
Core Imaging**

350 Campus Drive
Marlborough, MA
01752

Dear Nuclear Medicine Department,

GE Healthcare is pleased to announce that DaTscan™ (Ioflupane I 123 Injection) has recently been removed from the Schedules of the Controlled Substances Act. As a result of this descheduling action by the U.S. Drug Enforcement Administration (DEA), healthcare professionals and SPECT imaging centers no longer need to comply with the requirements for prescribing, storing, using, and disposing of Schedule II controlled substances when using DaTscan. This means that DaTscan will now be available to many more patients.

Effective October 17, 2015, there are some minor changes to the packaging and ordering of DaTscan:

- The labeling on both the vial and the lead shield will no longer have the DEA CII marking that denoted its status as a Schedule II controlled substance
- There will no longer be a tamper-proof sticker applied to the lead shield (this was a requirement of the drug's controlled substance status and is no longer needed)
- With the former Federal requirements now removed from ordering the product, DaTscan will be available with a reduced lead time. The Commercial team will distribute an updated ordering calendar

Changes to Custom-Designed Containers

In addition to packaging and labeling changes related to the descheduling of DaTscan, the Arlington Heights manufacturing facility is upgrading the custom-designed container (CDC) used to ship DaTscan, AdreView™ (Iobenguane I 123 Injection), thallium, Indium Oxine (Indium In-111 Oxyquinoline Solution), and Indiclор™ (High Purity Indium Chloride In-111 Sterile Solution). The CDC is the lead container that provides radiation shielding during transport. Previously, the above products were sent out in three different colors of CDCs. Effective October 17, 2015, all of these products will be shipped in a navy blue CDC. The CDC will have the same functional characteristics. However, the outside plastic is now a more robust design that will be less prone to showing scratches. We believe that the updated design of the new CDC better reflects the innovative technology that is used in the production of our products.

If you have any questions, please contact your GE Healthcare Sales Specialist.

Best regards,

Paul N. Ganes
Field Marketing Manager - Nuclear Medicine
GE Healthcare Life Sciences - Core Imaging

DaTscan™
Ioflupane I 123 Injection

© 2015 General Electric Company.
GE, the GE Monogram, DaTscan, AdreView, and Indiclор are
trademarks of General Electric Company.

October 2015 JB345864US Printed in USA