ENVELOPE

GE Healthcare

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USA

IMPORTANT

PRESCRIBING

INFORMATION

LETTER

September 11, 2015

IMPORTANT PRESCIBING INFORMATION

Subject: DaTscan™ (Ioflupane I 123 Injection)

Removal From the Schedules of the Controlled Substances Act

Dear Healthcare Provider:

The purpose of this letter is to inform you of important prescribing information about DaTscan (Ioflupane I 123 Injection), a radiopharmaceutical indicated for striatal dopamine transporter visualization using single-photon emission computed tomography (SPECT) brain imaging to assist in the evaluation of adult patients with suspected parkinsonian syndromes (PSs). In these patients, DaTscan may be used to help differentiate essential tremor from tremor due to PS (idiopathic Parkinson's disease, multiple system atrophy, and progressive supranuclear palsy). DaTscan is an adjunct to other diagnostic evaluations.

Change in the Scheduling of DaTscan

Since its approval in 2011, DaTscan has been listed by the Drug Enforcement Administration (DEA) as a Schedule II controlled substance. This has restricted use to healthcare professionals and SPECT imaging facilities registered with the DEA and able to comply with all of the requirements for prescribing, storing, using, and disposing of Schedule II controlled substances.

GE Healthcare has been working with the U.S. Food and Drug Administration (FDA), the DEA, and the movement disorder patient community to provide evidence that DaTscan did not pose a risk of abuse and, thus, did not require scheduling as a controlled substance. The DEA has now published formal notice in the *Federal Register* removing DaTscan from the Schedules of the Controlled Substances Act.

Prescriber Action

DaTscan remains a prescription medical imaging agent. However, as a result of descheduling by the 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. The prescribing information and the vial and shield labels for DaTscan have been changed to reflect the descheduling. These changes been implemented and will be incorporated into product shipped from the GE Healthcare manufacturing facility in Arlington Heights, Illinois.

Reporting Adverse Events

Healthcare providers and patients are encouraged to report adverse events in patients taking DaTscan to GE Healthcare at 800 654 0118. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 800 FDA 1088.

You can also contact our Medical Affairs department at 800 654 0118 (option 2, then option 3) if you have any questions about the information contained in this letter or about the safe and effective use of DaTscan.

This letter is not intended as a complete description of the benefits and risks related to the use of DaTscan. Please refer to the enclosed Full Prescribing Information.

For additional information, please visit www.datscan.com.

Sincerely,

Salvatore DeSena

Head of Medical Affairs, North America

GE Healthcare

Enclosure: Full Prescribing Information for DaTscan (Ioflupane I 123 Injection)