PRODUCT INDICATIONS AND USE: DaTscan™ (Ioflupane I 123 Injection) is 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). DaTscan may be used to help differentiate essential tremor from tremor due to PS (idiopathic Parkinson's disease [PD], multiple system atrophy [MSA], and progressive supranuclear palsy [PSP]). DaTscan is an adjunct to other diagnostic evaluations. DaTscan was not designed to distinguish among PD, MSA, and PSP. The effectiveness of DaTscan as a screening or confirmatory test and for monitoring disease progression or response to therapy has not been established.

Important Risk and Safety Information About DaTscan™ (Ioflupane I 123 Injection)

CONTRAINDICATIONS: DaTscan is contraindicated in patients with known hypersensitivity to the active substance, any of the excipients, or iodine. **WARNINGS AND PRECAUTIONS — Hypersensitivity Reactions:** Hypersensitivity reactions, generally consisting of skin erythema and pruritus, have been reported following DaTscan administration. **Thyroid Accumulation:** The DaTscan injection may contain up to 6% of free iodide (iodine 123 or I-123). To decrease thyroid accumulation of I-123, block the thyroid gland at least one hour before administration of DaTscan; failure to do so may increase the long-term risk for thyroid neoplasia. **ADVERSE REACTIONS:** In clinical trials, headache, nausea, vertigo, dry mouth, or dizziness of mild to moderate severity were reported. In postmarketing experience, hypersensitivity reactions and injection-site pain have been reported. **DRUG INTERACTIONS:** Drugs that bind to the dopamine transporter with high affinity may interfere with the DaTscan image. The impact of dopamine agonists and antagonists on DaTscan imaging results has not been established. **SPECIFIC POPULATIONS — Pregnancy:** It is unknown whether DaTscan can cause fetal harm or increase the risk of pregnancy loss in pregnant women. DaTscan should be given to pregnant women only if clearly needed. Like all radiopharmaceuticals, DaTscan may cause fetal harm, depending on the stage of fetal development and the magnitude of the radionuclide dose. Radioactive iodine products cross the placenta and can permanently impair fetal thyroid function. **Nursing Mothers:** It is not known whether DaTscan is excreted into human milk; however, I-123 is excreted into human milk. Because many drugs are excreted into human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to interrupt nursing after administration of DaTscan or not to administer DaTscan at all. Nursing women may consider interrupting nursing and pumping and discarding breast milk for six days after DaTscan administration to minimize risks to a nursing infant. **Pediatric Use:** The safety and efficacy of DaTscan have not been established in pediatric patients. **Geriatric Use:** There were no differences in responses between the elderly and younger patients that would require a dose adjustment. **Renal and Hepatic Impairment:** The effect of renal or hepatic impairment on DaTscan imaging has not been established. The kidney excretes DaTscan; patients with severe renal impairment may have increased radiation exposure and altered DaTscan images. **OVERDOSAGE:** It is unknown whether or not ioflupane is dialyzable. The major risks of overdose relate to increased radiation exposure and long-term risk for neoplasia. In case of radioactivity overdosage, frequent urination and defecation should be encouraged to minimize radiation exposure to the patient. **PROCEDURE — Radiation Safety:** DaTscan emits radiation and must be handled with safety measures to minimize radiation exposure to clinical personnel and patients.

Prior to DaTscan administration, please read the Full Prescribing Information.