

Report template for images with DaTscan™ (Ioflupane I 123 Injection)

DaTscan™
Ioflupane I 123 Injection

GE HealthCare suggests following reporting guidelines such as those in the referenced Society of Nuclear Medicine Practice Guideline for Dopamine Transporter Imaging with ¹²³I-Ioflupane SPECT.¹ This includes, but is not limited to:

History

- State whether the patient used potentially interfering drugs, and if so, which drugs
- Describe the route, dosage, and timing of sedation in relation to the scan, if sedation was administered

Technique

- State the time that elapsed between tracer injection and acquisition
- State the injected radiopharmaceutical dose
- State what criteria are used for the report interpretation (e.g., visual assessment, semi quantitative analysis, or comparison to reference database)

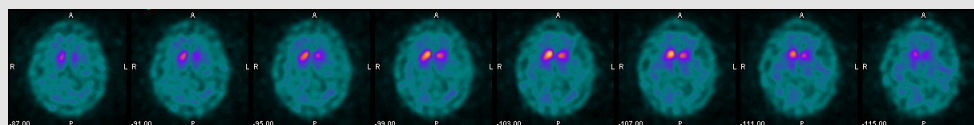
Report conclusion

- The conclusion should state whether a presynaptic dopaminergic deficit is present or absent. Abnormal findings indicate a presynaptic striatal dopaminergic deficit

An example of a report outline based on this might look like the following:

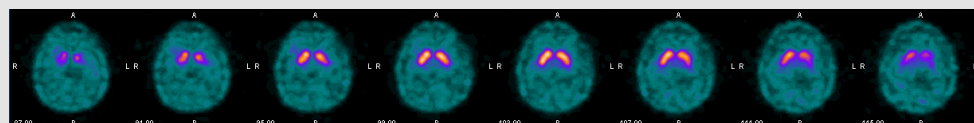
Abnormal scan example

- **Technique:** A thyroid-blocking agent was orally administered one hour prior to the intravenous administration of 4.8 mCi of 123-I-labeled DaTscan. Four hours later, a 30-minute SPECT scan of the brain was acquired. Data was reconstructed using iterative reconstruction and displayed in axial planes
- **Findings:** The images demonstrate reduced radiotracer uptake in the left and right striata, with more extensive involvement in the putamen, relative to caudate. Striatal reductions are more pronounced on the left caudate and putamen compared with the right
- **Impression:** Abnormal DaTscan image with evidence of striatal dopaminergic neurodegeneration



Normal scan example

- **Technique:** A thyroid-blocking agent was orally administered one hour prior to the intravenous administration of 5.0 mCi of 123-I-labeled DaTscan. Three hours later, a 30-minute SPECT scan of the brain was acquired. Data were reconstructed using iterative reconstruction and displayed in axial planes
- **Findings:** Bilateral, symmetric tracer uptake is noted in the striata. Nuclei uptake is distinct and above the background activity
- **Impression:** Normal and symmetric uptake of DaTscan in the striata without imaging evidence of striatal dopaminergic neurodegeneration



Please consult full guidelines for further information. Additional practice guidelines may be available. The examples herein are for illustrative purposes only and are not intended to be exhaustive. Technician should use professional judgment and consider all other relevant factors in completing the report. Inclusion of additional information may be necessary or advisable.

PRODUCT INDICATION AND USE

DATSCAN is indicated as an adjunct to other diagnostic evaluations for striatal dopamine transporter visualization using single photon emission computed tomography (SPECT) brain imaging in adult patients with:

- suspected Parkinsonian syndromes (PS) or
- suspected dementia with Lewy bodies (DLB).

IMPORTANT SAFETY INFORMATION ABOUT DATSCAN

CONTRAINDICATIONS

- DaTscan is contraindicated in patients with known serious hypersensitivity to ioflupane I 123.

WARNINGS AND PRECAUTIONS

- **Hypersensitivity Reactions:** Hypersensitivity reactions, including dyspnea, edema, rash, erythema, and pruritus, have been reported following DATSCAN administration.
- **Thyroid Accumulation:** DaTscan may contain up to 6% of free iodide (iodine-123). Thyroid uptake of iodine-123 may result in an increased long-term risk for thyroid neoplasia. To decrease thyroid accumulation of iodine-123, block the thyroid gland before administration of DaTscan.

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.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Radioactive iodine products cross the placenta and can permanently impair fetal thyroid function. Administration of a thyroid blocking agent is recommended before the use of DaTscan in a pregnant woman. All radiopharmaceuticals have potential to cause fetal harm. There are no available data on DaTscan use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Advise pregnant woman of the potential risks of fetal exposure to radiation with the administration of DaTscan.

RESOURCES

Customer Service: 800 292 8514

Reimbursement Hotline: 800 767 6664

Medical Affairs for Clinical and Scientific Support:

800 654 0118 (option 2, then option 3) or medical.affairs@ge.com

gehealthcare.com

- **Lactation:** Iodine 123 (I 123), the radionuclide in DaTscan, is present in human milk. There is no information on the effects on breastfed infants or on milk. Advise a lactating woman to interrupt breastfeeding and pump and discard breast milk for at least 6 days after DaTscan administration to minimize radiation exposure to a breastfeeding 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 elderly patients and younger patients that would require a dose adjustment observed in the parkinsonian syndrome studies.
- **Renal Impairment:** DaTscan is excreted by the kidney and patients with severe renal impairment may have increased radiation exposure and altered DaTscan images.

OVERDOSAGE

- The risks of overdose relate predominantly to increased radiation exposure, with the long-term risks for neoplasia. In case of overdosage of radioactivity, 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 [here](#) for additional Important Safety Information.

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 800 654 0118 (option 2, then option 1) or the FDA at 800 FDA 1088 or www.fda.gov/medwatch.

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1. Djang DS et al. *J Nucl Med.* 2012; 53(1): 154-163.

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April 2025
JB08376US