GE Healthcare

Report Template for Images with 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 ^{123}I-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 (eg, visual assessment, semi quantitative analysis, or comparison to reference database)

Diagnostic findings

- Mention any significant scan quality limitations, such as patient motion
- Describe the subjective visual impression of striatal binding compared with background activity. Examine both the caudate nuclei and the putamina for decreased activity; note which regions, if any, appear decreased. Note any significant asymmetries; mild asymmetry may occur in healthy individuals
- If abnormalities are present, report the location and intensity of the areas of decreased activity
- If semi quantitative analysis is performed, report the values and the reference range. An age-matched reference range would be preferable

Report conclusion

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

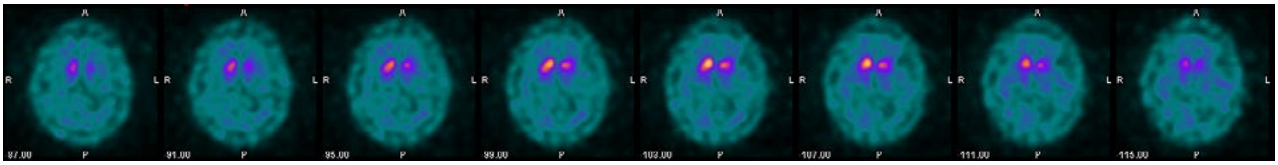
An example of a report outline based on this might look like the following:

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.

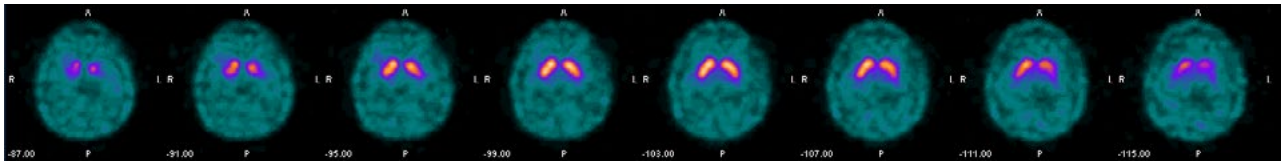


Normal scan example

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 additonial information may be necessary or advisable.

Please see Important Safety Information on the following page, and full Prescribing Information here.

DaTscan™
Ioflupane I 123 Injection

PRODUCT INDICATION 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). In these patients, 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 Safety Information About DaTscan

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

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
- **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
- **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 overdosage 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, here.

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.

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

Customer Service 800 292 8514

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

Reimbursement Hotline 800 767 6664

datscan.com **gehealthcare.com**

DaTscan™
Ioflupane I 123 Injection

May 2022 JB06894US