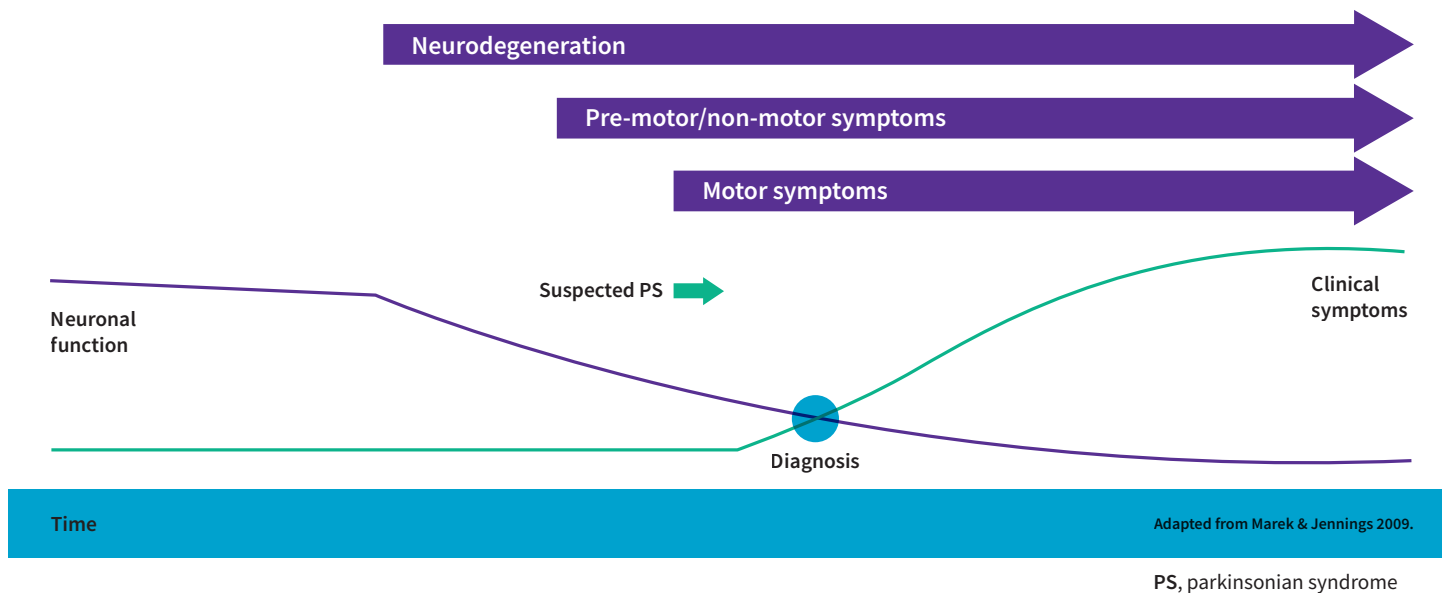




How can DaTscan aid in a movement disorder evaluation?

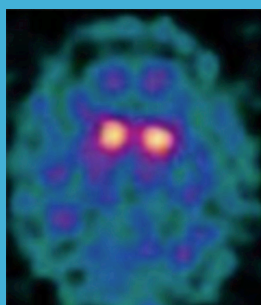


Dopaminergic degeneration occurs before clinical symptoms present.¹
Visualizing dopamine transporters can aid in providing a diagnostic direction for your patients.



Abnormal DaT density

Possible parkinsonian syndrome

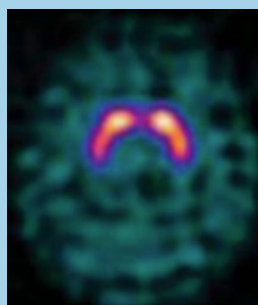


Conditions associated with a loss of dopaminergic neurons^{2,3}

- Parkinson's disease
- Multiple system atrophy
- Progressive supranuclear palsy

Normal DaT density

Possible non-parkinsonian syndrome



Conditions associated with no loss of dopaminergic neurons^{2,3}

- Essential tremor
- Drug-induced parkinsonism
- Vascular parkinsonism
- Psychogenic parkinsonism
- Dystonic tremor
- Alzheimer's disease

Symptoms may not always tell the whole story

- Patients may present with mild or atypical symptoms that do not match either Parkinsonian syndrome (PS) or essential tremor (ET) diagnostic criteria
- Symptoms can overlap or resemble the symptoms of many different movement disorders^{4,5}
- When visualizing a patient with motor symptoms, dopamine transporters can add valuable information concerning diagnosis, prognosis, and treatment



Brain SPECT imaging with DaTscan visualizes functioning dopamine transporters, providing valuable information for patient assessment, diagnosis, and prognosis²



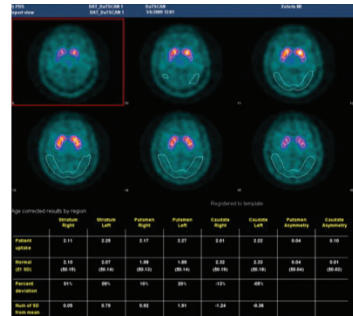
1 hour preinjection

At least one hour before the dose of DaTscan, the patient will be given another drug to prevent the radioactive iodine in DaTscan from going into your thyroid



injection of DaTscan

Before the test begins, DaTscan will be injected through an intravenous (IV) line



Scan: 3-6 hours postinjection

Because it takes time for the appropriate distribution of DaTscan to the brain, imaging will be done 3-6 hours after injection



Scan time: 30 min

For the imaging test, the patient will be asked to lie on a table, and a healthcare professional will position them on a headrest. A camera will be positioned above them, very close to their head. It should not touch them. The patient must try to remain as still as possible while the camera takes pictures (about 30 minutes).

Product Indications and Clinical Use – DaTscan™ (Ioflupane (123I) Injection)

DaTscan™ (Ioflupane (123I) Injection) is a radiopharmaceutical indicated for visualization of functional striatal dopamine transporter using single photon emission computed tomography (SPECT) brain imaging. In adult patients with suspected Parkinsonian Syndromes (PS), DaTscan SPECT imaging may be used as an adjunct to other established evaluations to help differentiate essential tremor from tremor due to PS related to idiopathic Parkinson's Disease (PD), multiple system atrophy (MSA) and progressive supranuclear palsy (PSP). DaTscan is unable to discriminate between PD, MSA and PSP.

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

CONTRAINDICATIONS: DaTscan is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. **WARNINGS AND PRECAUTIONS:** Radiopharmaceuticals should be used only by those health professionals who are appropriately qualified in the use of radioactive prescribed substances in or on humans. As in the use of any other radioactive material, care should be taken to minimize radiation exposure to patients consistent with proper patient management, and to minimize radiation exposure to occupational workers. **HYPERSENSITIVITY REACTIONS:** Hypersensitivity reactions have been reported following DaTscan administration. Prior to administration appropriate resuscitation equipment should be available. **THYROID ACCUMULATION of I-123:** The DaTscan injection may contain up to 6% of free iodide (iodine 123). Accumulation of radioiodine in the thyroid gland may result in long term risk for thyroid neoplasia. To decrease thyroid accumulation of iodine 123, administer a thyroid blocking agent at least 1 hour before administration of DaTscan. **ADVERSE REACTIONS:** In clinical trials, headache, nausea, and dizziness were commonly reported as adverse events. Less commonly reported adverse events included vertigo, increased appetite, dry mouth, formication, dysgeusia and injection site pain. In post marketing experience, serious and nonserious hypersensitivity reactions as well as reports of injection-site pain, headache, dizziness, formication (paresthesia), dysgeusia, nausea and dry mouth have been reported. **DRUG INTERACTIONS:** Drugs that bind to the dopamine transporter with high affinity can interfere with DaTscan binding, therefore may affect the images obtained. The impact of dopamine agonists and antagonists has not been established. **SPECIFIC POPULATIONS — Pregnancy:** Since adequate reproduction studies have not been performed in animals to determine whether DaTscan affects fertility in males or females, has teratogenic potential, or has other adverse reactions on the fetus, this radiopharmaceutical preparation should not be administered to pregnant women unless it is considered that the benefits to be gained outweigh the potential hazards to the fetus. **Nursing Mothers:** It is not known whether ioflupane (123I) is secreted in human milk, therefore, if administration is considered necessary, breast-feeding should be interrupted for 3 days and substituted by formula feeding. During this time, breast milk should be expressed at regular intervals and the expressed feeds should be discarded. **Pediatric Use:** The safety and efficacy of DaTscan in children aged 0 to 18 years has not been established, therefore DaTscan is not recommended in children. **Renal and Hepatic Impairment:** Formal studies have not been carried out in patients with significant renal or hepatic impairment. DaTscan is not recommended in cases of moderate to severe renal or hepatic impairment. **OVERDOSAGE:** In cases of overdose of radioactivity, frequent micturition and defecation should be encouraged to minimize radiation dosage to the patient. Care should be taken to avoid contamination from the radioactivity

eliminated by the patient using such methods. **Reporting Side Effects:** You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada.

Prior to administration, please read the Product Monograph for DaTscan™ and the Important Safety Information, which is available by calling Customer Service 1 800 387 7146 or through an email request to canadainfo@ge.com.

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.

Reporting Side Effects

To report SUSPECTED ADVERSE REACTIONS, contact GE HealthCare at 1 800 654 0118 (option 2, then option 1), or email canadainfo@ge.com to request an adverse events form, or fax to 905 847 5849 to request an adverse events form.

Adverse reactions can also be reported to Health Canada as follows:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

References:

1. Marek K, Jennings D. Can we image premotor Parkinson's disease? *Neurology*. 2009;72:S21-S26.
2. DaTscan Product Monograph (September 27, 2019)
3. Kägi G, Bhatia KP, Tolosa E. The role of DAT-SPECT in movement disorders. *J Neurol Neurosurg Psychiatry*. 2010; 81:5-12.
4. Hauser RA, Grosset DG. [123I]FP-CIT (DaTscan) SPECT brain imaging in patients with suspected parkinsonian syndromes. *J Neuroimaging*. 2012;22:225-230.
5. Pahwa R, Lyons KE. Early diagnosis of Parkinson's disease: recommendations from diagnostic clinical guidelines. *Am J Manag Care*. 2010;16:S94-S99.

Please use the following language when ordering:
Brain SPECT imaging with DaTscan



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