GE Healthcare

Dose Calibrator Process for Iodine 123

Please review the steps below to properly calibrate your dose calibrator for measurement of Iodine 123 in a glass vial or syringe. The recommended dose of DaTscan is 111 MBq to 185 MBq (3mCi to 5 mCi) administered intravenously.

Reading DaTscan in the Dose Calibrator

1. Place the vial into the dose calibrator and read the number of mCi detected.
2. See the table below to determine time and dose (for example, at 10:00 AM ET, the vial should read no greater than 5.55 mCi).
3. Manually adjust the potentiometer to record the correct number of mCi for the time (in the example above, this would be 5.55 mCi).
4. Draw everything out of the vial using a syringe (for consistency, use the same brand and size of syringe moving forward).
5. Place the vial back into the calibrator and record the residual mCi present in the vial.
6. Subtract the residual reading (step 5) from the original vial reading. This determines how many mCi of DaTscan are in the syringe.
7. Place the syringe into the dose calibrator.
8. Adjust the potentiometer to the expected reading (original vial reading minus residual reading from Step 6).
9. This is the setting to read all future syringes of DaTscan, assuming the same syringe brand and size are maintained. Repeat steps 1 to 9 as needed or per local regulations.
10. Please see the recomended dose. This table contains values outside the recomended dose for your measurement reference. Each patient should be be administered a dose as recomended in the **full Prescribing Information**.

Decay Table (ET)

Time	Activity	Time	Activity	Time	Activity	Time	Activity
08:00	6.17 mCi	11:00	5.27 mCi	14:00	4.50 mCi	17:00	3.85 mCi
08:30	6.01 mCi	11:30	5.13 mCi	14:30	4.39 mCi	17:30	3.75 mCi
09:00	5.85 mCi	12:00	5.00 mCi	15:00	4.27 mCi	18:00	3.66 mCi
09:30	5.70 mCi	12:30	4.87 mCi	15:30	4.16 mCi	18:30	3.57 mCi
10:00	5.55 mCi	13:00	4.74 mCi	16:00	4.05 mCi	19:00	3.48 mCi
10:30	5.41 mCi	13:30	4.62 mCi	16:30	3.95 mCi	19:30	3.39 mCi

Activities are based on 12:00 ET/Reference Date (Calibration Date).
Decay Equation: (EXP(-(LN(2)*t)/13.221hr))* Label Activity.

Please see Important Safety Information About DaTscan, here, and the full Prescribing Information, here.

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 (iodine123 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 post marketing 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, 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.

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

DaTscan™
Ioflupane I 123 Injection

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